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ORIGINAL ARTICLE

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Heart failure is associated with increased risk of all-cause mortality after transvenous lead extraction: A systematic review and meta-analysis

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Abstract

Background: Transvenous lead extraction (TLE) is increasingly considered in cardiac implantable electronic device management. Heart failure (HF) might be associated with mortality risks after the TLE procedure. This study aims to assess mortality risk in HF patients undergoing TLE.

Method: We searched MEDLINE and Embase databases from inception to June 2022 to identify articles that included patients with and without HF who underwent TLE, which reported mortality in both groups. The pooled effect size was calculated with a random-effects model and 95% CI to compare post-TLE mortality between the two groups.

Results: Eleven studies were included in the analysis. Each left ventricular ejection fraction (LVEF) increased by 1% was associated with reduced mortality by 2% (HR = 0.98, 95% CI: 0.97–0.99, $I^2 = 74.9\%$, $p < .01$). The presence of HF compared to those without HF was associated with higher mortality rates (OR: 3.04, 95% CI: 2.56–3.61, $I^2 = 0.0\%$, $p < .531$). There was a significant increase in the mortality rates in patients with New York Heart Association (NYHA) function class III (OR: 2.29, 95% CI: 1.29–4.06, $I^2 = 0.0\%$, $p = .498$) and NYHA IV (OR: 8.5, 95% CI: 2.98–24.3, $I^2 = 0.0\%$, $p = .997$).

Conclusions: Our study found that post-TLE mortality decreases by 2% as LVEF increases by 1%, also mortality is higher in patients with NYHA III and IV.

KEYWORDS
heart failure, left ventricular ejection fraction, mortality, transvenous lead extraction

1 | INTRODUCTION

Based on the Framingham Heart Study, the mortality rate after diagnosis of heart failure (HF) in the USA was around 10% at 30 days, 20–30% at 1 year, and 45–60% over 5 years of follow-up in the general population.[1] On the other hand, CHF with certain characteristics qualifies for automated implantable cardioverter defibrillator (AICD) or cardiac resynchronization therapy (CRT).[2–4] Also, the expanding use of the permanent pacemaker in the United States[5] evokes further lead management discussions. While the leadless pacemaker

seems to be associated with promising outcomes, transvenous pacemakers still play a crucial role in most patient populations.

The guideline has suggested transvenous lead extraction (TLE) as one of the most important managements of infected cardiac implantable electronic devices (CIED).[6] Device infection, with an incidence of 0.68%–2.18%,[7,8] has been reported to be the most common indication of TLE in the recent era.[9,10] To improve the procedural outcome, consensus guidelines recommend evaluating the risk factor of adverse events before performing the procedure.

Patients who underwent TLE have been reported to have more medical comorbidities.[5] The prevalence of HF among TLE patients ranges from 20.2% to 32.3%, and many studies reported CHF as a mortality predictor.[10–12] We sought to analyze the existing literature to assess whether CHF is associated with increased all-cause mortality among the patients who underwent TLE.

2 | METHODS

2.1 | Search strategy

Two investigators (FT and MCT) independently searched for published studies indexed in PUBMED and EMBASE databases from inception to June 2022, which included the terms "heart failure" and "lead extraction", using the search strategy described in Figure 1. Only English-language publications were included. A manual search for additional pertinent studies and review articles using references from retrieved articles was also completed.

2.2 | Inclusion criteria

The eligibility criteria included the following:

1. Cohort study (prospective or retrospective) and descriptive studies reporting endpoint of all-cause mortality after the transvenous lead extraction procedure.
2. Reported hazard ratio (HR), odds ratio (OR), and relative risk (RR) with 95% confidence intervals (CIs).
3. Participants without HF as controls.

Study eligibility was independently determined by two investigators (FT and MCT), and differences were resolved by mutual consensus. The Newcastle–Ottawa quality assessment scale was used to evaluate each study in three domains: recruitment and selection of the participants, similarity, comparability between the groups, and ascertainment of the outcome of interest among cohort studies.

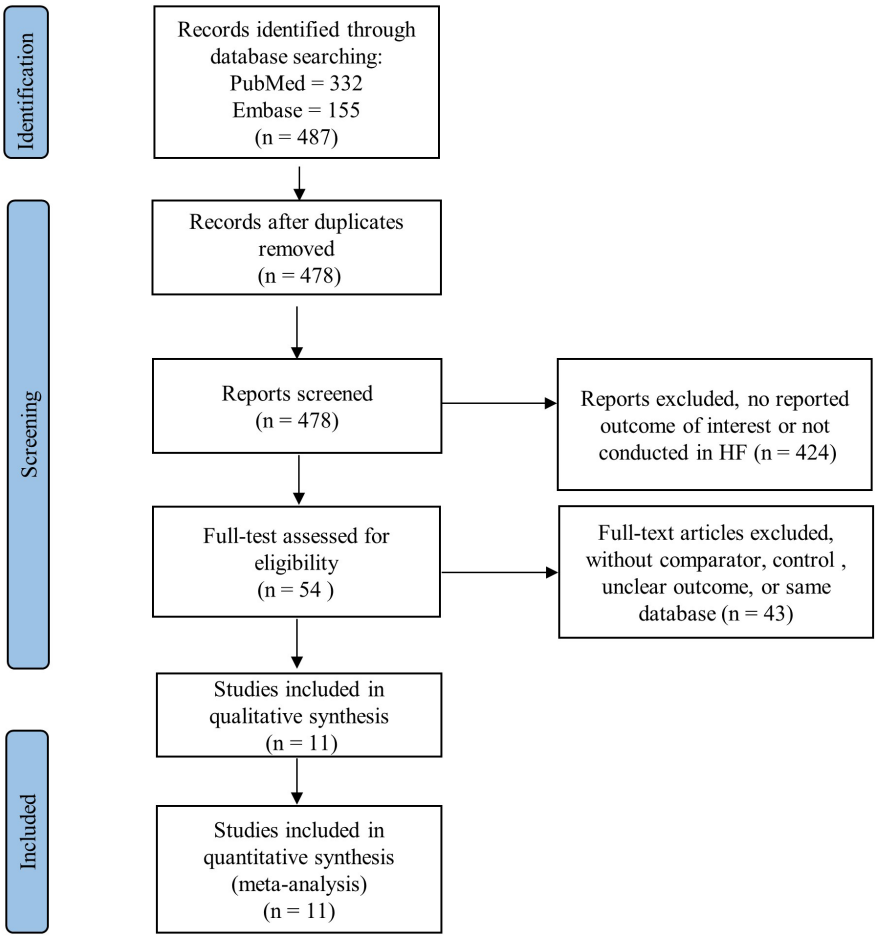

FIGURE 1 Preferred reporting items for systematic reviews and meta-analyses (PRISMA) flow diagram of the search strategy and included studies.

TABLE 1 Summary of the included studies and the clinical characteristics.

Authors	Country of origin	Year	Study design	description of study	Participants description	indication for extraction	Exclusion criteria	Methods
Al-Hijji et al	United States	2016	Retrospective cohort	Outcomes of lead extraction with and without subsequent device reimplantation.	Consecutive patients underwent TLE in the two reference institutes between 2001 and 2012.	Device infection: 52.6%, all-other indications: 47.4%.	Patients who did not survive to hospital discharge or did not have at least 1 year of follow-up were excluded from the study.	Medical records review- Mayo Clinic, Rochester, MN and University of California San Diego Medical Center
Barakat et al	United States	2018	Prospective cohort	The procedural profiles and clinical outcomes of TLE in patients with CIED infection based on kidney function.	Consecutive patients underwent TLE following CIED infection in the reference institute between 1996 and 2012	Device infection: 100%.	–	Registry based- Cleveland Clinic
Brunner et al	United States	2014	Retrospective cohort	The safety and efficacy of chronic endovascular pacemaker and ICD lead extraction.	Consecutive patients who underwent TLE in the reference institute between August 1996 and August 2011.	Device infection: 42.7%, lead malfunction: 34.5%, Device upgrade: 16.2%, Others: 6.2%	Patients who did not meet the criteria of lead extraction were excluded.	EMR-Cleveland Clinic
Deckx et al	Belgium	2014	Retrospective cohort	Predictors of 30-day and 1-year mortality after transvenous lead extraction	Consecutive patients underwent TLE in reference institute between January 2005 and December 2011	Lead malfunction and device upgrade: 47.7%, Local or pocket infection: 34.7%, CIED systemic infection: 17.6%.	Patients requiring primary open cardiac surgery	Medical records review- University hospitals Leuven
DiCori et al	19 European countries	2019	Retrospective cohort	Clinical impact of antithrombotic therapy in TLE safety and efficacy	Patients enrolled in ESC-EHRA-ELECTRA registry	Device infection: 53%, Non-functional lead: 38%, All other indications: 9%.	-	Registry based- ELECTRa registry
Hosseini and Rozen	United States	2019	Cross-sectional study	Safety and in-hospital outcomes of TLE associated with device-related infection	Consecutive patients who underwent TLE between January 1, 2003, and September 31, 2015	Device infection: 100%.	Hospitalization with any other procedures within the same hospital stay with similar perioperative complication profiles as lead extraction	National inpatient sample (NIS)/ ICD-9 codes
Mehta et al	UK	2021	Prospective cohort	Long-term mortality following TLE and predictors of mortality.	Consecutive patients undergoing TLE in the reference center between 2000 and 2019	Device infection: 53.1%, All other indications: 46.9%.	Patients who did not survive to discharge	Medical records review

Mean LVEF	Exposure group	Reference	Population no.	Male	Mean age	Follow up duration	Outcome definition by authors	Conclusion by authors	HR or OR reported[a] by authors
N/A	N/A	N/A	678	65%	69.2 ± 17.1	4.2 ± 3.1 years	All-cause mortality within study follow-up		HR, LVEF (%) 0.98 (0.96–1.00)
40.7 ± 15.6	NYHA II, III, IV	NYHA I	1420	73.70%	68.06 ± 14.93	30-day	All-cause mortality within 1-mo of TLE	NYHA functional class is independent predictor of mortality in one month after TLE	HR, NYHA II: 1.0 (0.39–2.55), NYHA III: 1.06 (0.38–2.91), NYHA IV: 9.60 (2.24–41.56) and HR: LVEF (%): 0.99 (1.00–1.01)
37.5 ± 8.7	NYHA II, III, IV and EF ≤ 15%	NYHAI or no HF and EF > 15%	2999	69.80%	66.45 ± 3.5	30-day	All-cause mortality within 30-days of TLE	–	OR, NYHA II: 1.3 (0.6–2.8), NYHA III: 2.0 (1.0–4.0), NYHA IV: 8.5 (2.4–29.9) and OR, LVEF ≤ 15%: 2.0 (1.1–5.0)
N/A	CHF	No CHF	176	68.8	63 ± 16	30-day, 1-year	All-cause mortality within 30-days and 1-year following TLE	HF was not significantly associated with 1-year mortality	OR, CHF 1.327 (0.337–4.556)
45.5 ± 14.7	NYHA III, IV	No HF, NYHA I, NYHA II	3510	72.20%	64.9 ± 15.6	In-Hospital death	All-cause in-hospital mortality after TLE	NYHA FC III/IV is an independent predictor of death for any cause.	HR, NYHA III: HR 2.82 (1.16–6.82), NYHA IV: 6.59 (1.78-24.46)
N/A	CHF	No CHF	59 082	70%	69.5 ± 3.4	30-day	All-cause in-hospital mortality after TLE	CHF is an independent predictor of in-hospital mortality	OR, CHF: 3.28 (2.48–4.34)
45.4 ± 14	CHF	No CHF	1151	72.50%	65 ± 14.7	66.4 ± 49.9 months	All-cause in-hospital mortality after TLE	–	HR, CHF: 1.11 (0.81–1.51) and HR, LVEF%: 0.98 (0.97–0.99)

TABLE 1 (Continued)

Authors	Country of origin	Year	Study design	description of study	Participants description	indication for extraction	Exclusion criteria	Methods
Merchant et al	United States	2015	Retrospective cohort	Long-term outcomes of ICD lead extraction for infectious and noninfectious indications.	Consecutive patients who underwent TLE of ICD leads in the reference center from January 2007 to October 2013	Lead failure: 61.8%, Device infection: 32.5%, all other indications: 5.7%.	–	Medical records review and institutional database-Emory university hospital midtown
Narui et al	United States	2021	Retrospective cohort	Risk factors associated with repeat infection and mortality in patients who underwent CIED extraction for infection.	Consecutive patients who underwent TLE following CIED infection in the reference center from August 2003 to May 2019	Device infection: 100%.	–	EMR-Vanderbilt university medical center
Polewczyk et al	Poland	2016	Retrospective cohort	Factors influencing early and long-term survival in patients undergoing TLE in the setting of LRIE.	Consecutive patients who underwent TLE following LRIE in the reference center between 2006 to 2015	Definite LRIE: 80%, possible LRIE: 20%	–	Medical records review
Tajstra et al	Poland	2021	Retrospective cohort	Risk factors for in-hospital complications post TLE and 12-month mortality and morbidity.	Patients enrolled in SILCARD registry	Not clearly defined	–	Registry based-Silesian Cardiovascular Database (SILCARD) registry /ICD-9 and ICD-10 codes

Abbreviations: CHF, congestive heart failure; CI, confidence interval; CIED, cardiovascular implantable electronic device; HF, heart failure; HF, heart failure; HR, hazard ratio; ICD, International Classification of Diseases; LRIE, Lead-related infective endocarditis; LVEF, Left ventricular ejection fraction; NYHA, New York heart association; OR, odds ratio; TLR, transvenous lead extraction.

[a]Reported as median 95% CI.

2.3 | Data extraction

A standardized data collection form was used to obtain the following information from each study: title of study, name of the first author, year of study, year of publication, country of origin, number of participants, demographic data of participants, the method used to identify cases and controls, the method used to diagnose outcomes of interest (mortality and procedural complications), the average duration of follow-up, confounders that were adjusted, adjusted effect estimates with 95% CI, and covariates that were adjusted for the multivariable analysis.

To ensure accuracy, two investigators independently performed this data extraction process (FT and MCT). Any data discrepancy was resolved by referring to the original articles.

2.4 | Definition of HF

HF is a complex clinical syndrome with symptoms and signs that result from any structural or functional impairment of ventricular filling or ejection of blood. The most common terminology used to describe the severity of HF is the New York Heart Association (NYHA) functional classification. NYHA class is a subjective assessment by a clinician based on the severity of symptoms and physical activity, including class I patients with no limitations in physical activity resulting from their HF. NYHA class II includes patients who are comfortable at rest but have slight symptoms resulting from HF (dyspnea, fatigue, light-headedness) with ordinary activity. NYHA class III includes patients who are comfortable at rest but have symptoms of HF with less than ordinary activity. NYHA class IV

Mean LVEF	Exposure group	Reference	Population no.	Male	Mean age	Follow up duration	Outcome definition by authors	Conclusion by authors	HR or OR reported[a] by authors
31.8 ± 15.9	N/A	N/A	508	69%	60.6 ± 15.2	866 ± 798 days	All-cause mortality within 30-days of TLE, all-cause mortality within study follow-up	Lower LVEF is a predictor of mortality	HR, EF (%): 1.04 (1.02–1.07)
41 ± 16	CHF	No CHF	496	73.20%	65 ± 14	499.75 ± 142.86 days	All-cause mortality within study follow-up	Congestive HF is an independent predictor of increased mortality following TLE	HR, CHF: 1.48 (1.00–2.19)
49.15 ± 14.47	N/A	N/A	500	68.60%	66.96 ± 13.90	30-days; 3.0 ± 2.14 years	All-cause mortality within 30-days of TLE	Decreased LVEF has unfavorable effect on long-term survival in patients with LRIE	HR, LVEF (%) 1.346 (1.208–1.499)
N/A	CHF	No CHF	835	68.50%	70.92 ± 1.24	12-month	12-month all-cause mortality	A history of HF affected 12-month mortality	OR, CHF: 3.65 (1.76–7.59)

includes patients who cannot carry out any physical activity without symptoms and have symptoms at rest.[4]

2.5 | Outcome definition

The mortality was defined as all-cause mortality at any time after the TLE procedure. To study the mortality impact of HF, eligible studies were divided into three different categories based on the reported variable. The first group studies reported the impact of the severity of HF on mortality based on the impact of each 1% increase or decrease in LVEF with mortality. The other group consisted of studies that compared the impact of the presence of an HF diagnosis on mortality. The Final group consisted of studies that reported the impact of the severity of HF on mortality based on the presence of NYHA II, NYHA III, or NYHA IV compared to NYHA I.

2.6 | Statistical analysis

We performed a meta-analysis of the included cohort studies using a random-effects model. We pooled the point estimates of HR or OR from each study using the generic inverse-variance method of DerSimonian and Laird. The heterogeneity of effect size estimates across these studies was quantified using the I^2 statistic. The I^2 statistic ranges in value from 0% to 100% ($I^2 < 25\%$, low heterogeneity; $I^2 = 25\%–50\%$, moderate heterogeneity; and $I^2 > 50\%$, substantial heterogeneity). A sensitivity analysis was performed to assess the influence of the individual studies on the overall results by omitting one study at a time. Publication bias was assessed using a funnel plot and Egger's regression test ($p < .05$ was considered significant). Potential sources of heterogeneity from clinical characteristics were analyzed with subgroup analysis. Fitted random-effects model with truncated Knapp–Hartung method meta-regression was performed

to evaluate the association between the NYHA in each study and the risk of all-cause mortality. All data analyses were performed using Stata SE Statistical Software: Release 14.1: StataCorp LP, StataCorp 2015.

2.7 | Sensitivity analysis

We used a sequential exclusion strategy, as described by Patsopoulos et al, to examine whether overall estimates were influenced by the substantial heterogeneity observed.[13] In accordance with Cochrane, evidence of publication bias was examined through funnel plots if there were more than 10 available studies. Funnel plot asymmetry was further confirmed with Egger's test.

3 | RESULTS

3.1 | Description of included studies

Our search strategy yielded 487 potentially relevant articles (332 articles from PubMed and 155 from EMBASE). After excluding nine duplicate articles, 478 articles underwent title and abstract review. Later, 424 articles were excluded since they did not report the outcome of interest (all-cause mortality), were not cohort or descriptive with the nonexposure group, or were not conducted in patients with heart failure studies, leaving 54 articles for full-length article review. Forty three of the 54 studies were excluded, as they were either descriptive studies without a comparator or the same group of authors using the same database. Therefore, eight retrospective[10,14–20] and two prospective cohort studies[9,21] and one cross-sectional study[22] with 71 355 patients (mean age: 68.9 ± 4.8 years, male: 70.2%) were included in this meta-analysis. Figure 1 outlines the search and literature review process. Summary of the included studies and the clinical characteristics are shown in Table 1.

Majority of the TLE procedures in the included studies were done in the setting of device infections as indicated in Table 1. Of the total 11 studies, six studies (4172 patients, mean age: 65.8 ± 14.7 years, male: 71.9%) reported an association of each 1% decrease in LVEF with mortality rate. Only one study from Brunner et al[10] reported binary analysis using the absolute cut-off of EF ≤15% with the odds ratio 2.0 (95% CI: 1.1–5.0). Mean LVEF of the included studies is shown in Table 1.[9,14,17–19,21] Also, four studies reported an association of mortality with a diagnosis of heart failure (61 244 patients, mean age: 69.4 ± 3.6 years, male: 70.1%).[9,15,20,22] Among those, two studies defined HF diagnosis based on the presence of appropriate International Classification of Diseases (ICD), 9th or 10th Revision diagnosis code for HF[20,22] and the other two defined HF based on review of medical records.[9,15] Association of mortality with severity of HF was reported in two studies based on NYHA functional class (6509 patients, mean age: 65.6 ± 10.0 years, male: 71.1%).[10,16]

3.2 | Meta-analysis results

Analysis of studies that had investigated the association of 1% increase in LVEF with mortality[9,14,17–19,21] showed every EF increased by 1% will reduce mortality by 2% (HR = 0.98, 95% CI: 0.97–0.99, $I^2 = 74.9\%$, $p < .05$) as depicted in Figure 2. Potential publication bias was assessed with a funnel plot of overall mortality in terms of an increase in LVEF, as shown in Figure 3. The funnel plot was asymmetric for HR of overall mortality. By Egger's test, there was significant publication bias regarding overall mortality ($p = .028$), as depicted in Figure S1.

Analysis of the studies that reported an association of mortality with a diagnosis of HF[9,15,20,22] showed that patients with HF had a significantly higher risk of overall all-cause mortality (OR = 3.04, 95% CI: 2.56–3.61, $I^2 = 0$, $p = .531$) as depicted in Figure 4. A funnel plot of overall mortality in terms of HF diagnosis is shown in Figure 5. The funnel plot was asymmetric for OR of overall mortality. By Egger's

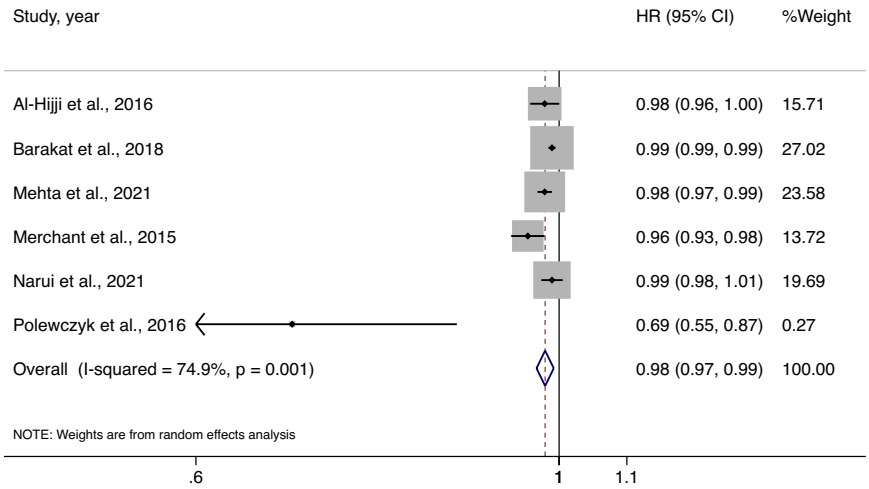

FIGURE 2 (Central illustration). Forest plot of decrease in an overall hazard ratio (HR) of mortality according to the 1% increase in LVEF.

test, there was significant publication bias regarding overall mortality ($z = 12.74$, $p < .01$) as depicted in Figure S2.

Analysis of the studies that reported an association of mortality with severity of HF based on NYHA functional class[10,16] showed that NYHA III (OR: 2.29, 95% CI: 1.29–4.06, $I^2 = 0\%$, $p = .498$) and NYHA IV (OR: 8.5, 95% CI: 2.98–24.3, $I^2 = 0.0\%$, $p = .997$) were associated with higher mortality rates as Figure 6 outlines the association. Although a trend is seen by increasing NYHA class, the odds of overall-cause mortality did not show a significant difference in meta-regression analysis with restricted maximum likelihood (REML) and Knapp–Hartung modification ($p = .07$), as depicted in Figure 7. Due to a limited number of publications, assessment of heterogeneity and possible publication bias was not possible.

3.3 | Quality assessment of included studies

The quality of each study was evaluated by two independent authors (FT and MCT). The Newcastle–Ottawa scale (0–9) was used to evaluate included studies on three domains: selection, comparability, and outcomes. Higher scores represent higher study quality. The score of each study ranged from 8 to 9, which reflected high quality. Intra-study risks of bias of included studies and quality assessment are also described in Tables S1 and S2.

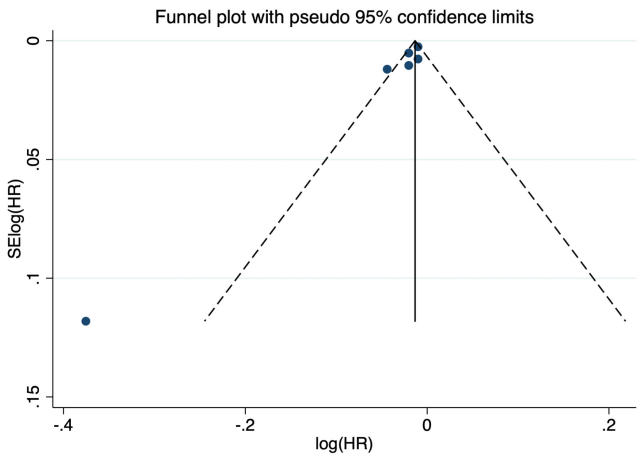

FIGURE 3 Funnel plot of decrease in overall mortality according to the 1% increase in LVEF.

4 | DISCUSSION

While HF could be a potential indication for CIED implantation, to our knowledge, the present systematic review and meta-analysis are the first to assess the association between HF and post-TLE all-cause mortality. Our analysis shows that: (1) Every EF increased by 1% will reduce post-TLE all-cause mortality by 2% (HR = 0.98); (2) A diagnosis of HF is significantly associated with increased overall all-cause mortality in TLE patients; and (3) NYHA classes III and IV are associated with increased mortality.

Each 1% decrease in LVEF% was found to increase the overall mortality by 2%. The included studies for each 1% change in LVEF% ranged a follow-up duration from 30 days to 4 years. This finding is notable as Strange et al had previously shown that a greater than 10% decrease in LVEF increases the adjusted risk of mortality to twofold higher than the group without such changes over a 5-year follow-up.[23] This finding could be explained by the fact that patients who are referred for CIED implantation generally have lower ejection fraction based on the indications for the device. Our findings are consistent with the existing studies suggesting that patients with LVEF < 15% have a poorer prognosis.[10] Interestingly, no difference was observed in another study with an LVEF% cutoff of <35%.[12]

In a cross-sectional study of outcomes of over 12 000 hospitalizations in the United States, Hosseini and Rozen reported CHF to be a significant predictor of mortality after TLE procedures increasing the odds by three times (OR: 3.28, 95% CI: 2.48–4.34).[22] Our study of pooled cohorts found about the same numbers (OR: 3.04, 95% CI: 2.56–3.61). These findings are also consistent with the existing studies suggesting that HF is associated with increased all-cause mortality after TLE on multivariate analysis.[9,20]

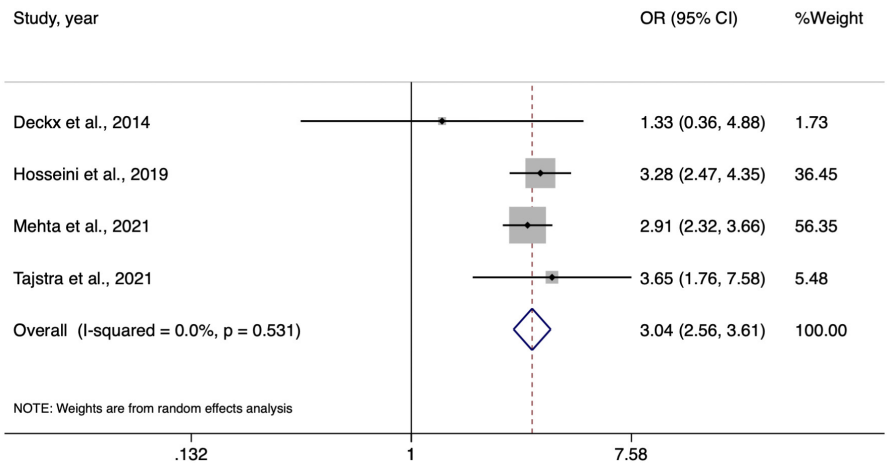

FIGURE 4 Forest plot of decrease in overall mortality according to the HF.

Based on the European Lead Extraction ConTRolled registry (ELECTRa) study, infections make up 53% of the indications for lead extractions.[16] That said, a systematic review and meta-analysis by Ngiam et al[24] found that the risk of mortality after CIED infection is nearly two times higher in patients with a history of HF (OR: 1.92, 95% CI: 1.419–2.603). Our study is coherent with these findings as none of the included studies were done in a sterile extraction setting.

An association of a higher NYHA functional class with a higher risk of death was demonstrated by previous studies. A retrospective study of 1915 patients by Jacheć et al showed patients with NYHA class III and IV have 3.06 times (HR: 3.06; $p < .001$) higher risk of mortality 30-day following TLE in comparison with NYHA I and II.[25] Similar results were reproduced with longer term follow-up, where the worse functional class was associated with 3.07 times more risk of 1-year mortality following TLE (HR: 3.76; $p < .0001$).[26] Our findings are consistent with the existing studies suggesting that NYHA class III and IV are associated with increased all-cause mortality after TLE on multivariate analysis.[10,16,21,26] In the present study, we observed a potentially increasing trend in mortality with increasing NYHA class ($p = .073$) but statistically insignificant likely due to underpowered. This is consistent with the reported trend by a previous study.[25] In this study, only 1.01% of patients in NYHA I and II classes died in 30 days after the TLE procedure, while the same rate was 4.6% for patients in the NYHA III and IV classes ($p < .001$).[25]

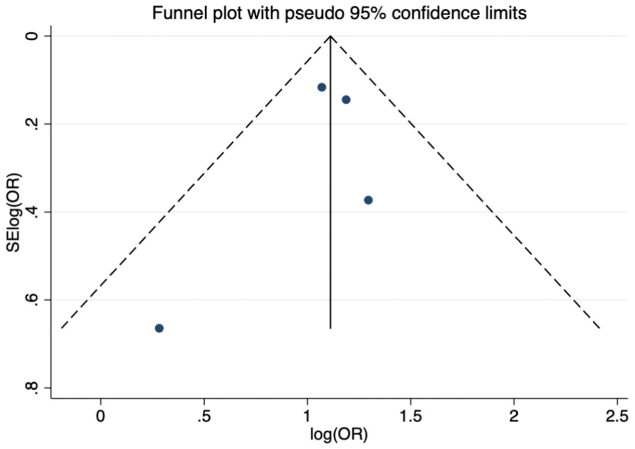

FIGURE 5 Forest plot of decrease in overall mortality according to the HF.

Various perioperative factors may have contributed to the higher postoperative mortality observed for patients with heart failure, even in low-complexity procedures. In a study by Faxén et al the factors that modified the risk associated with HF the most were age, hypertension, and AF in patients undergoing elective surgery and age, IHD, and AF in patients undergoing emergency surgery.[27]

There also may be intraoperative or postoperative factors associated with general anesthesia among patients with heart failure attributable to intraoperative or postoperative hypotension independent of surgical complexity.[28]

Historically, HF is a well-known independent risk factor for complications after noncardiac surgeries[27,29] and there are commonly practiced models to predict the cardiac risk of major noncardiac surgery.[30] These models are helpful in shared decision making before interventions. Similarly, Jacheć[25] et al suggested SAFeTY as a scoring tool for quantifying procedural success and complications after TLE. In SAFeTY, the scoring system includes the sum of lead dwell times, anemia, female, previous procedures before TLE, and young patients under the age of 30. Our findings suggest that HF should be incorporated into the risk scoring tool, given that HF is a significant risk factor for procedural complications and mortality after TLE.[25,26]

Lead extraction procedures are generally considered safe and in the setting of a definite device-related infection, complete device

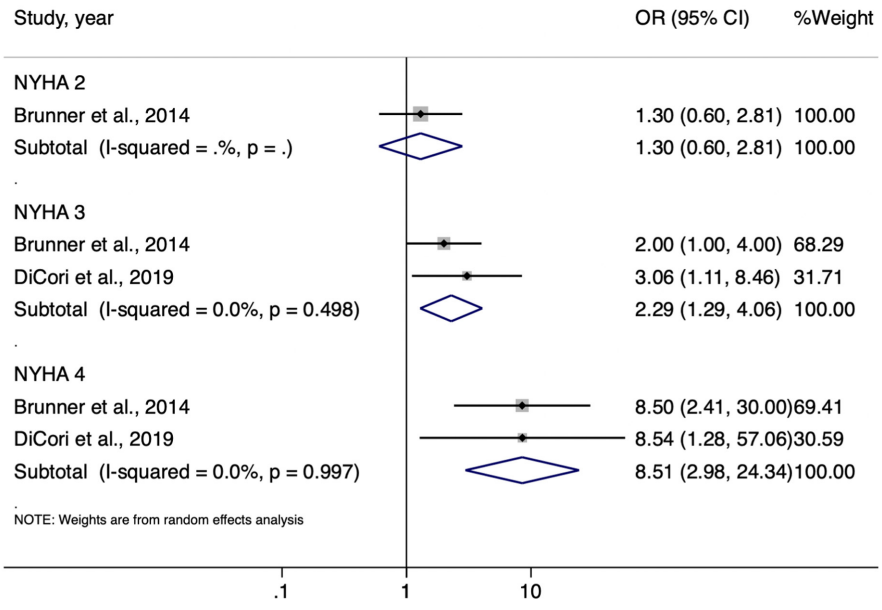

FIGURE 6 Forest plot of overall mortality according to the severity of clinical heart failure determined by NYHA class.

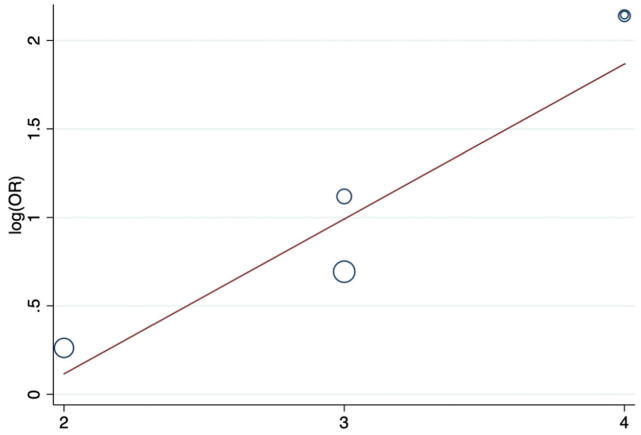

FIGURE 7 Meta-regression analysis of overall mortality according to the severity of clinical heart failure determined by NYHA class.

removal is a class I recommendation.[6] Naturally, majority of the TLE procedures included in the current analysis were done in the setting of device infection. Although our study showed higher risk of mortality in patients diagnosed with HF or suffering from NYHA III or IV functional, in case of a device infection benefits of source control should be taken into consideration. One interpretation of these findings is that patients with heart failure, especially symptomatic with NYHA class III or IV, should be counseled regarding their higher risk of postprocedural mortality, in addition, optimizing their cardiac function specifically LVEF% preoperatively should be well considered.

5 | STUDY LIMITATIONS

There are several potential limitations of the present analysis. First, the sterile and infectious indications of TLE were pooled together, whereas there might be different outcomes in patients with HF based on indications for TLE. Second, HF was defined as the presence of the diagnosis of HF of any kind, which was primarily based on ICD coding, whereas HF is a clinical syndrome with a wide spectrum, and results need to be adjusted based on HF classification and stages. Third, only one study from Brunner et al reported binary analysis using the absolute cutoff of EF ≤ 15%. We can only conclude that EF ≤15% increases the odds of mortality up to 2-fold from one study. Unfortunately, there is insufficient published data to perform a pooled analysis on binary analysis by EF cut-point. Fourth, due to the scarcity of study data, we had to disregard time in the analysis, although mortality risk could be a time-sensitive matter. Fifth, despite extensive adjustments in the registries included in this study, we cannot rule out potential residual confounding. Lastly, this study is based on published studies, and the possibility of publication bias cannot be excluded.

6 | CONCLUSION

Every EF increased by 1% will reduce post-TLE all-cause mortality by 2%. HF diagnosis is significantly associated with increased overall all-cause mortality after TLE. NYHA class III-IV is associated with higher mortality. These findings should be taken into clinical consideration before TLE procedures.

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CONFLICT OF INTEREST

All authors have no relationships relevant to the contents of this paper to disclose.

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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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