Predictors of perforation during lead extraction: Results of the Canadian Lead ExtrAction Risk (CLEAR) study

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BACKGROUND Transvenous lead extraction can have serious adverse events, such as cardiac or vascular perforation. Risk factors have not been well characterized.

OBJECTIVE The purpose of this study was to identify factors associated with perforation and death, and to characterize lead extraction in a large contemporary population.

METHODS We performed a retrospective multicenter study examining patients undergoing lead extraction at 8 Canadian institutions from 1996 through 2016. Demographic and clinical data were used to identify variables associated with perforation and mortality using logistic regression modeling.

RESULTS A total of 2325 consecutive patients (age 61.9 ±16.5 years) underwent extraction of 4527 leads. Perforation rate was 2.7% (63/2325) and 30-day mortality was 1.6% (38/2325), with mortality of 0.4% due to perforation (10/2325). Variables associated with perforation included no previous cardiac surgery (odds ratio [OR] 3.33; 95% confidence interval [CI] 1.54–7.19; $P = .002$), female sex (OR 3.27; 95% CI 1.91–5.60; $P < .001$); left ventricular ejection fraction ≥40% (OR 2.81; 95% CI 1.28–6.14; $P = .010$); lead age >8 years (OR 2.64; 95% CI 1.52–4.60; $P < .001$); ≥2 leads extracted (OR 2.49; 95% CI 1.23–5.04; $P = .011$); and diabetes (OR 2.12; 95% CI 1.16–3.86; $P = .014$). Variables associated with death included infection as indication for extraction (OR 3.85; 95% CI 1.38–10.73; $P = .010$); anemia (OR 3.14; 95% CI 1.38–6.61; $P = .003$), and patient age (OR 1.04; 95% CI 1.01–1.07; $P = .012$).

CONCLUSION Risk factors associated with perforation in lead extraction include no history of cardiac surgery, female sex, preserved left ventricular ejection fraction, lead age >8 years, ≥2 leads extracted, and diabetes.

KEYWORDS Complications; Defibrillator; Lead extraction; Pacemaker; Tamponade

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Introduction

Commiserate with the increasing frequency and complexity of cardiac implantable electronic device (CIED) implantations is the need for a safe and effective method for removing CIED system leads. The objective of transvenous lead extraction (TLE) is removal of the CIED lead from surrounding

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fibrous adhesions while minimizing damage to the associated cardiovascular structures. Over the past 30 years, TLE techniques have evolved significantly, moving from simple traction to the incorporation of sophisticated dedicated toolsets that have improved the clinical effectiveness and safety of TLE procedures, of which the excimer laser is one of the most common and effective tools.[1] Depending on the series, the complete procedural success of extraction has been estimated at 95%–97% ("clinical success" of 98%–99% if partial extractions are included).[2–4] As a counterbalance to the high procedural success is the realization that TLE carries a risk of significant complications. Although there are few comparative trials of TLE techniques, the published single-center or multicenter series indicate major life-threatening complications occur in 0.4%–3.5% of patients, with a 0%–0.8% incidence of death.[2,3]

Unfortunately, there are very few comparative trials of lead extraction techniques and even fewer that are randomized. Despite widespread and growing utilization, current data on CIED extraction outcomes are largely limited to case series from single high-volume centers with experienced operators. As the population requiring extraction is getting older with increasingly complex device systems and more comorbidities, international societies have called for the establishment of pan-national registries to address the lack of information on the safety and efficacy of contemporary TLE.[5,6]

Our objective was to evaluate the composite efficacy and safety of TLE, including intraprocedural, postprocedural, and short-term complications, and to determine risk factors for perforation and death using a pan-national multicenter cohort of consecutive patients undergoing TLE. Secondary objectives were to describe the demographics, clinical characteristics, indications, and procedural success rates of TLE on a national level. Finally, we endeavored to understand variation among centers and determine a population-based rate of outcomes for this procedure.

Methods

A national multicenter retrospective cohort study was conducted on 2325 consecutive adult patients undergoing a TLE procedure across 8 Canadian sites between July 1996 and July 2016. After providing written informed consent, all patients underwent powered TLE using the excimer laser catheter (Philips Image Guided Therapy Devices, Colorado Springs, CO) or mechanical dilators/cutters (Cook Medical, Bloomington, IN; or Philips, Colorado Springs, CO). Patients whose leads were explanted using manual traction alone were excluded from the current study. The decision to perform a TLE procedure was left to the participating physicians. No specific protocol or recommendations for the lead extraction procedure, intraoperative materials or lead extraction techniques, and/or treatment after the procedure was mandated. The study complied with the Declaration of Helsinki and was approved by the local ethics review board of each participating institution.

Data collection

Variables collected at the time of the extraction procedure included patient demographics, cardiovascular history, noncardiac comorbidities, CIED history, echocardiographic data, and variables related to the extraction procedure. Data were obtained from existing provincial or institutional registries, the majority of which were prospectively entered. These data were supplemented using electronic medical records, paper charts as needed, vital statistics, and device clinic records.

Outcomes

The primary outcome measures assessed were cardiac or vascular perforation, as well as 30-day mortality. Cardiac or vascular perforations were defined as injury requiring sternotomy, thoracotomy, pericardiocentesis, or chest tube insertion. Secondary outcomes included other periprocedural complications such as pericardial effusion, pleural effusion or pneumothorax not requiring intervention, venous thrombosis and arm swelling, injury at the venous entry site, blood transfusion, pulmonary embolism, and lead fragment migration.

Statistical analysis

Continuous data are summarized by mean ± SD or median (interquartile range) where appropriate, and were analyzed using the Student *t* test or Wilcoxon rank sum test for continuous variables. Categorical variables are expressed as frequency (percentage) and were compared using the χ^2 or Fisher exact test.

To explore the association of variables with the main outcomes of perforation or 30-day mortality, a generalized estimating equations (GEE) logistic regression with clustering on center was performed. By comparing some assumed working correlation structures, such as independent, exchangeable, first-order autoregressive, and unstructured, the one that presented with the smaller GEE fit criteria value was selected to work with the final model. The multiple logistic regression model was generated using a backward selection algorithm with statistical significance of inclusion and exclusion at $P < .05$ and variables selected using clinical judgment. Candidate variables for the perforation risk model were chosen in part based on previously published associations.[7–15] Left ventricular ejection fraction (LVEF) was treated as a categorical variable as ≥40% or <40%. Leads extracted were dichotomized as ≥2 leads removed as indicated by the data. Mean lead age was modeled as the age of the oldest lead and was dichotomized at 8 years in the model. Spearman correlation coefficients and Kendall tau correlation coefficients were calculated to assess the relationship between center volumes and perforation rate, respectively.

Missing data at baseline were infrequent (<1% for most variables); however, LVEF and lead fixation mechanism were missing in 13.5% and 9.5% of patients (11.8% of leads), respectively. The descriptive statistical analysis and tests were conducted using only cases without missing values

("complete case analysis"). For regression analysis, imputations were performed with the multiple imputation approach under the assumption "missing completely at random," and the number of imputations to be performed was specified as 10 for higher accuracy. The results using complete data and imputed data are reported separately.

All tests were 2- sided, and $P < .05$ was considered significant. All statistical analyses were performed using SAS software Version 9.4 (SAS Institute, Cary, NC).

Results

Population data

A total of 2325 consecutive patients who underwent extraction of 4527 leads between July 1996 and July 2016 were included in the study. Mean age was 61.9 ± 16.5 years, and 29% (n = 675) were female. Median body mass index (BMI) was 26.3 kg/m^2 (23.5–30.1). Comorbidities included hypertension (47.0%), atrial fibrillation (41.0%), and diabetes (15.3%). A minority of the patients had renal failure (acute renal failure in 2.0%, chronic kidney disease in 9.9%). A majority of patients had an underlying cardiomyopathy (66.2%), with mean LVEF of 44.8% ± 15.6%. Previous cardiac surgery had been performed in 29.6% of patients. Patient baseline characteristics are listed in Table 1.

Site variation

Significant variability was seen with respect to center volumes (from 61 to 983 patients) as well as the indications for TLE. Some centers used extraction primarily for the class I indication of removal for infection, whereas others were more aggressive with class II indications.[6]

Indication for TLE

The most common indication for TLE was infection (48.6%), followed by nonfunctional or dysfunctional leads (42.6%). A minority of cases were performed for vascular access (7.7%), at the time of upgrade (6.3%), or for skin erosion (9.5%). Some patients had multiple indications listed for extraction. Of the cases categorized as infection, evidence of endocarditis was noted in 11.1% of total cases, and isolated pocket infection was noted in 82.0% (Tables 1 and 2).

Details of TLE procedures

Of the 4527 leads removed, 28.7% were defibrillator leads and 71.3% were pacemaker leads. The majority of TLE procedures were performed by a cardiovascular surgeon (79.7%), in an operating room (60.3%) or hybrid room (25.3%). A laser was required for the removal of 83.6% of individual leads in 95% of patients. Mechanical rotating sheaths (Cook Evolution, Cook Medical; or Philips TightRail, Philips, Andover, MA) were used exclusively for 11.3% of leads in 5% of patients. A minority of leads were removed with cautery (0.5%) or manual traction (11.7%) (Tables 2 and 3). Thus, all patients in the study required removal of at least 1 lead utilizing laser or mechanical rotating sheaths.

Table 1 Patient baseline characteristics

Variable	Total* (N = 2325) n (%)†	Missing
Demographics		
Age (y)	61.9 ± 16.5	0
Female sex	675 (29.0)	0
BMI (kg/m^2)	26.3 (23.5–30.1)	172
Cardiac condition		
Previous cardiac surgery	685 (29.6)	11
Atrial fibrillation	946 (41.0)	17
Ventricular arrhythmias	874 (38.0)	24
Cardiomyopathy		123
Dilated	274 (12.4)	
Ischemic	709 (32.2)	
Arrhythmogenic right ventricular cardiomyopathy	55 (2.5)	
Hypertrophic	134 (6.1)	
Other	285 (12.9)	
Evidence of endocarditis	255 (11.1)	32
LVEF within 6 months of the procedure (%)	44.8 ± 15.6	313
Severe pulmonary hypertension	32 (1.4)	52
Hemoglobin (g/L)	130.9 ± 19.7	288
eGFR (mL/min)	71.0 (57.0–89.0)	865
Major comorbidities		
Acute renal failure	46 (2.0)	15
Chronic renal failure	229 (9.9)	9
Dialysis	48 (2.1)	8
COPD	190 (8.2)	8
Diabetes	355 (15.3)	116
Hypertension	1092 (47.0)	16
Device type and lead dwell time		
Primary function of current cardiac implantable electronic device system		11
Pacings	1167 (50.4)	
ICD	906 (39.2)	
CRT-P	22 (1.0)	
CRT-D	219 (9.5)	
Dwell time (y)‡	6.9 ± 6.5	472

Other values are given as mean ± SD or median (interquartile range).

BMI = body mass index; COPD = chronic obstructive pulmonary disease; CRT-D = cardiac resynchronization therapy–defibrillator; CRT-P = cardiac resynchronization therapy–pacemaker; eGFR = estimated glomerular filtration rate; ICD = implantable cardioverter-defibrillator; LVEF = left ventricular ejection fraction.

*Total includes all 8 sites.

†Percentage calculated based on the complete cases, and unavailable cases set as missing.

‡Calculated based on the number of lead extracted.

Cardiac perforation and death

A total of 38 patients (1.6%) died in the 30 days after lead extraction. Of these patients, 10 experienced a perforation (0.4%) and 28 died without perforation. Another 53 patients experienced perforation and survived. Thus, a total of 63 patients had a perforation (2.7%). The locations of the perforations are detailed in Table 4 and Supplemental Table 1. Seven patients with a history of cardiac surgery had a clinically significant perforation, 2 of whom died. The majority of patients with perforation had hypotension (93.7%), with 33.9% experiencing circulatory collapse. A total of 85.7% of cardiac

Table 2 Operation details

Variable	Total* (N = 2325) n (%)†	Missing
Operator		8
Cardiovascular surgeon	1847 (79.7)	
Electrophysiologist	470 (20.3)	
Location of the extraction		7
Operating room	1397 (60.3)	
Electrophysiology laboratory	311 (13.4)	
Hybrid room	610 (25.3)	
Indication for removal‡		10
Infection	1124 (48.6)	
Chronic pain	130 (5.6)	
Thrombosis or venous stenosis	178 (7.7)	
Nonfunctional/dysfunctional lead	985 (42.6)	
Device advisory (recall)	332 (14.3)	
Upgrade	145 (6.3)	
Erosion	219 (9.5)	
Other	53 (2.3)	

*Total includes all 8 sites.
†Percentage calculated based on the complete cases, and unavailable cases set as missing.
‡Some patients had multiple indications for extraction.

perforations were treated with surgical repair, usually through a sternotomy (85.5%). Pericardiocentesis was required in 19.4% of cases, and 36.5% required a chest tube. Minor complications occurred in 11.4% of the cohort. Table 4 lists the periprocedural complications.

Perforation and mortality risk models

Supplemental Tables 2 and 3 present univariate analysis of candidate variables and their statistical significance for the outcomes of perforation and mortality, respectively. Multiple logistic regression analysis revealed a cohesive model with 6 variables. Female sex (odds ratio [OR] 3.27; 95% confidence interval [CI] 1.91–5.60; $P < .001$), leads that had a longer dwell time (OR 2.64; 95% CI 1.52–4.60; $P < .001$), number of leads extracted (OR 2.49; 95% CI 1.23–5.04; $P = .011$), and diabetes (OR 2.12; 95% CI 1.16–3.86; $P = .014$) were significantly associated with risk of perforation. LVEF <40% (OR 2.81; 95% CI 1.28–6.14; $P = .010$) and previous cardiac surgery (OR 3.33; 95% CI 1.54–7.19; $P = .002$) were highly protective of cardiac or vascular perforation. This model was unchanged whether patients with missing data were excluded or dealt with via multiple imputation. The c statistic of this model was 0.80 (Table 5). The risk factors for perforation are shown in Figure 1.

Multiple logistic regression analysis identified 3 variables that were significantly associated with 30-day mortality: increasing age (OR 1.04; 95% CI 1.01–1.07; $P = .012$), anemia (OR 3.14; 95% CI 1.38–6.61; $P = .003$), and infection as the indication for TLE (OR 3.85; 95% CI 1.38–10.73; $P = .010$). The c statistic of this model was 0.81. This model was also unchanged whether patients with missing data were excluded or dealt with via multiple imputation (Table 6).

Table 3 Summary of lead level variables

Variable	Total* (N = 4527) n (%)†	Missing
Lead chamber		114
Right atrium	1552 (35.2)	
Left ventricle	226 (5.1)	
Right ventricle	2635 (59.7)	
Lead fixation mechanism		536
Active	2243 (56.2)	
Passive	1748 (43.8)	
Lead type		32
ICD	1289 (28.7)	
Pacing	3206 (71.3)	
Lead under advisory		146
Yes	542 (12.4)	
No	3839 (87.6)	
Lead status at time of extraction		102
Active	3633 (82.1)	
Abandoned	792 (17.9)	
Tools for extraction		36
Cautery	21 (0.5)	
Mechanical sheaths	509 (11.3)	
Laser	3753 (83.6)	
None	534 (11.7)	
Lead extraction success		169
Total	4119 (94.5)	
Partial	175 (4.0)	
Electrode tips remnant only	64 (1.5)	
Lead extraction entry point		215
Left subclavian/axillary/cephalic	3854 (83.1)	
Right subclavian/axillary/cephalic	410 (9.5)	
Other	46 (1.1)	

Analyzed with respect to lead, not patient.
ICD = implantable cardioverter-defibrillator.
*Total includes all 8 sites.
†Percentage calculated based on the complete cases, and unavailable cases set as missing.

Notably, center volume, BMI, lead type (implantable cardioverter-defibrillator vs pacemaker), number of defibrillator coils, and fixation type were not associated with lead perforation or 30-day mortality on multivariable analysis.

Discussion

The retrospective Canadian Lead Extraction Risk (CLEAR) study captures the majority of TLEs that occurred in Canada over a 20-year period, representing a population-based analysis of the outcomes of a powered TLE cohort. The study observed the following significant findings. (1) A total of 2.7% of lead extraction procedures were complicated by perforation, and 1.6% of patients died in the 30 days after extraction. However, the majority of deaths occurred in the absence of perforation, and the majority of patients who experienced a perforation survived. (2) Risk factors for death included advanced age, anemia, and infection as the indication for extraction. (3) Risk factors for perforation included female sex, comorbid diabetes, preserved LVEF, multiple leads extracted, older lead age, and absence of previous cardiac surgery.

Table 4 Complications

Variable	Total* (N = 2325)
Total perforations	63 (2.7)
Death within 30 days	38 (1.6)
Both death and perforation	10 (0.4)
Location of perforation†	
Cardiac	42 (1.8)
Vascular	31 (1.3)
Unknown	1 (0.04)
Perforation evidenced by‡	
Circulatory collapse	21 (33.9)
Hypotension	59 (93.7)
Echocardiography	22 (35.5)
Intervention for perforation‡	
Pericardiocentesis	12 (19.4)
Thoracotomy/sternotomy	53 (85.5)
Chest tube	23 (36.5)
Surgical repair	54 (85.7)
Other intervention	20 (33.3)
Hematoma at the surgical site	91 (3.9)
Delayed pericardial effusion	30 (1.3)
Delayed pleural effusion	63 (2.7)
Pneumothorax	12 (0.5)
Venous thrombosis at site of extraction (confirmed by venogram or ultrasound)	16 (0.7)
Arm swelling (side of surgery)	18 (0.8)
Lead fragment migration	26 (1.1)
Blood transfusion	
Related to blood loss during surgery	78 (3.4)
Not related to blood loss during surgery	7 (0.3)
Pulmonary embolism	10 (0.4)
No. of minor complications	
0	1764 (75.9)
1	297 (12.8)
≥2	264 (11.4)

Values are given as n (%).
*Total includes all 8 sites.
†See Supplemental Table 1 for a full breakdown of the perforation locations.
‡Percentage calculated based on the complete cases of perforation observed.

Table 5 Multivariable predictors for perforation

	Regression without multiple imputation		Regression with multiple imputation	
Variable	OR (95% CI)	*P* value	OR (95% CI)	*P* value
Female sex	3.27 (1.91–5.60)	<.001	3.26 (1.94–5.49)	<.001
Diabetes	2.12 (1.16–3.86)	.014	1.97 (1.10–3.54)	.024
No previous cardiac surgery	3.33 (1.54–7.19)	.002	3.27 (1.52–7.02)	.002
LVEF ≥40%	2.81 (1.28–6.14)	.010	2.77 (1.26–6.11)	.012
No. of leads extracted (≥2)	2.49 (1.23–5.04)	.011	2.75 (1.37–5.52)	.005
Oldest lead age >8 y	2.64 (1.52–4.60)	<.001	2.42 (1.41–4.17)	.001

Firth's penalized likelihood approach was used. *P* = .94 (0.64 with multiple imputation) from Hosmer and Lemeshow goodness of fit test showed a c statistic of 0.80 (0.80 with multiple imputation).
CI = confidence interval; LVEF = left ventricular ejection fraction; OR = odds ratio.

Our study found a higher rate of perforation compared to the results of many experienced single-center publications. At 2.7%, this result was of interest, particularly when coupled with the low rate of mortality associated with that perforation. The perforation rate in the LExICon (Lead Extraction in the Contemporary Setting) study was 1.4% but represented mostly highly experienced operators.[3] Although National Cardiovascular Data Registry data would be thought to be equally representative, it shows a much lower perforation rate. National Cardiovascular Data Registry data examine a very different and lower-risk population, with much fewer powered extractions and a lower age of lead dwell time.[12] Our findings show a relatively low rate of mortality, with cardiac or vascular perforations of 15.9%. Many series that report perforation have mortality rates in the 30% to 50% range in this setting.[9,16] We hypothesize that this reflects robust surveillance and reporting, along with immediate surgical intervention in the represented Canadian centers.

Perforation and mortality risk models

The CLEAR study was designed to reduce uncertainty regarding the risk factors for cardiac or vascular perforation in the setting of powered TLE. Most studies that examine perforation do so in the context of grouped endpoints ("major adverse cardiac events"), with multiple endpoints combined and then analyzed, with the notable exception of the recent ELECTRa (European Lead Extraction ConTRolled)) registry subanalysis.[14] Combined endpoints have the advantage of making analysis easier and provide a broader view of TLE outcomes but are less specific with regard to making critical clinical and technical intraoperative decisions. Being able to more clearly understand the issue of perforation as a stand-alone event not only allows for better consultations and preoperative decision-making but also improves the consent process and could be a very useful tool to identify high-risk cases and manage risk on the day of the procedure. Although early in its utilization (but not available at the time of our cohort), the Bridge Balloon (Philips, Colorado Springs, CO) has the potential to significantly reduce mortality with its deployment.[17] It cannot be deployed effectively once an injury has occurred, so it should be ready before the laser/mechanical sheaths being applied. The corollary to this is that if one is not able to effectively risk prognosticate preoperatively, then the balloon would have to be deployed in every extraction to be effective. This requires significant resources. Ultimately, effective risk prognostication could potentially allow an operator to safely and accurately categorize patients as low risk and manage them differently from the higher-risk patients.

Our model provides the most comprehensive view to date of a patient's risk of perforation. It encompasses both specific factors that increase risk (female sex, older lead dwell time, multiple leads removed) and those that are protective (lower LVEF and previous cardiac surgery) and therefore may lend

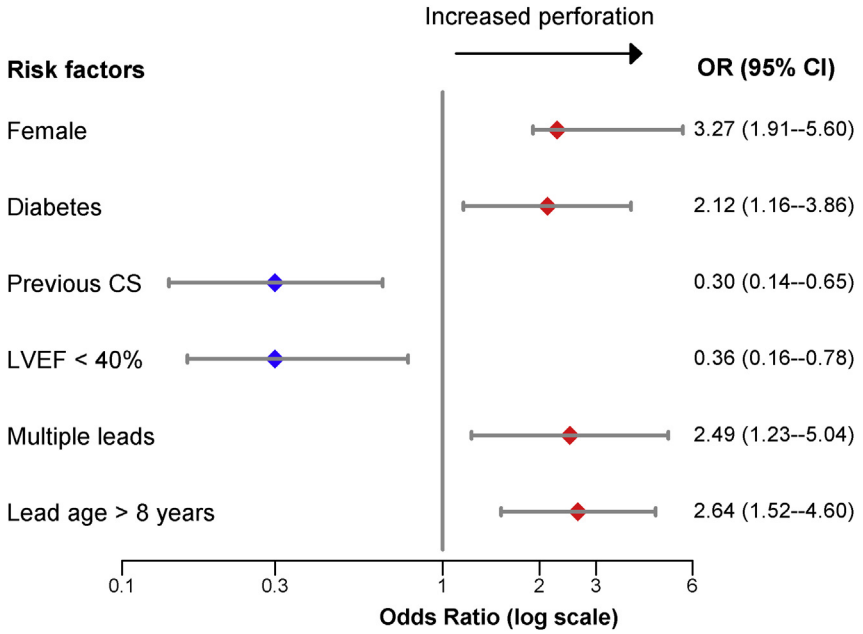

Figure 1 Forest plot of risk factors affecting perforation during transvenous lead extraction. *Blue* indicate protective; *red* indicates risk. CI = confidence interval; CS = cardiac surgery; LVEF = left ventricular ejection fraction; OR = odds ratio.

itself to a risk scoring system that could be deployed in a heart team approach preoperatively. All of the factors identified for the model are reasonably precise (narrow CI) with large effect sizes.

Diabetes is a novel risk factor for perforation. We hypothesize that diabetes may contribute to excessive calcification of intravascular leads similar to arterial calcification in atherosclerosis, and this increases the difficulty of the extraction.[18] The association of diabetes with perforation is worthy of further study. Diabetes has been shown to be associated with increased mortality in the lead extraction population but not with perforation.[19] It also should be noted that previous attempts at risk models for TLE may have been significantly hampered if LVEF and previous cardiac surgery were not included, as they function in the opposite direction as the other factors and would cloud any analysis if not taken into consideration.

Table 6 Multivariable predictors for 30-day mortality

	Regression without multiple imputation		Regression with multiple imputation	
Variable	OR (95% CI)	*P* value	OR (95% CI)	*P* value
Age (y)	1.04 (1.01–1.07)	.012	1.03 (1.01–1.06)	.019
Anemia*	3.14 (1.38–6.61)	.003	2.73 (1.36–5.48)	.005
Indication: infection	3.85 (1.38–10.73)	.010	3.41 (1.43–8.17)	.006

Firth's penalized likelihood approach was used. $P = .39$ (0.49 with multiple imputation) from Hosmer and Lemeshow goodness of fit test showed a c statistic of 0.81 (0.78 with multiple imputation).

CI = confidence interval; OR = odds ratio.

*Anemia: hemoglobin <120 g/L (female) or hemoglobin <130 g/L (male).

The pathophysiological mechanism for each of these patient and device factors is worthy of discussion. Female sex has been established in many series as a clinical factor that increases the risk of major adverse events and perforation.[7,20] The mechanism for this finding is not clear, but the smaller caliber and possibly thickness of great vessels and the heart in women may be the key. Lead dwell time and the number of leads extracted are both device factors that increase the risk of dense adhesions and lead–lead interaction. This seems to make TLE substantially more difficult and requires increased intraoperative use of powered/mechanical sheaths to cut through these lead-to-vessel and lead-to-lead adhesions.

Previous cardiac surgery has been described as a potential protective factor. However, the occurrence of some perforations in this setting and the extreme level of complexity when an injury in that setting occurs have obscured the picture. Previous cardiac surgery almost invariably creates external adhesions around the superior vena cava and right heart and therefore can easily contain a full-thickness disruption of the vessel as the pericardium itself provides an additional barrier. However, this does not prevent perforation into a free pleural space on the right side of the superior vena cava and in the extrapericardial portions. Should a perforation occur in the setting of previous cardiac surgery, this event would more likely be fatal due to the difficulty of gaining access in a redo sternotomy. Finally, in our study, low LVEF had a protective effect. The mechanism is likely due to the significant chamber and great vessel dilation that occurs in cardiomyopathy. This would cause the leads to sit further from the vessel wall (an opposite effect to that seen in women). We were unable to find any association between a patient's BMI and perforation. No clear pathophysiological

mechanism is understood for this association, and it has not been well validated in other studies.

It should be emphasized that risk scoring is not equivalent to predicting a clinical outcome. Risk models are simply extrapolations of where risk existed with a past series of patients. Even if they are highly representative, they cannot predict future events. One of the great modifiers is operator experience. As the larger, more experienced, single-center series describe, event rates in the setting of highly experienced operators likely are better. In our series, we were unable to stratify risk according to experience of the operator, and there was no clear association between center volume and perforation.

Study limitations

The study is retrospective and therefore data acquisition may be limited. This study is limited mostly to procedures where the laser was used to facilitate extraction and should only be extrapolated to situations where the laser is used.

Conclusion

Although TLE can have serious complications such as perforation or death, the rates of adverse events are relatively low. The risk of undertreated or untreated infection likely is higher than the risk of TLE, especially when performed in high-volume centers. This study has identified multiple risk factors, including novel ones, as strongly associated with these events. This will allow for better risk stratification of patients undergoing TLE and allow practitioners and patients to plan appropriately and enhance the safety of TLE.

Appendix

Supplementary data

Supplementary data associated with this article can be found in the online version at https://doi.org/10.1016/j.hrthm.2021.10.019.

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