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CLINICAL RESEARCH
Leads and lead extraction

Major cardiac and vascular complications after transvenous lead extraction: acute outcome and predictive factors from the ESC-EHRA ELECTRa (European Lead Extraction ConTRolled) registry

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Aims

We aimed at describing outcomes and predictors of cardiac avulsion or tear (CA/T) with tamponade and vascular avulsion or tear (VA/T) after transvenous lead extraction (TLE) in the ESC-EHRA European Lead Extraction ConTRolled (ELECTRa) registry.

Methods and results

A total of 3555 consecutive patients of whom 3510 underwent TLE at 73 centres in 19 European countries were enrolled. Among 58 patients (1.7%) with procedure-related major complications, 49 (84.5%) patients (30 CA/T and 19 VA/T) presented cardiovascular complications requiring pericardiocentesis, chest tube positioning and/or surgical repair. The mortality was 20% in patients with tamponade due to CA/T and 31.6% in patients with VA/T. Pericardiocentesis as first manoeuvre followed by rescue surgical repair was highly effective in case of CA/T (93.8%). At multivariate analysis, CA/T with tamponade was more common in RIATA lead extraction, female patients, leads with a mean dwelling time more than 10 years, and when ≥3 leads were extracted or multiple sheaths required. Occlusion or critical stenosis of superior venous access and the leads mean dwelling time more than 10 years were independent predictors for VA/T, while mechanical dilatation was an independent predictor of a lower incidence of this complication as compared to the use of powered sheaths.

Conclusions

In the ELECTRa registry, RIATA lead extraction and superior venous access occlusion/thrombosis are two new independent predictors for cardiac tamponade and major vascular complications, respectively. The use of mechanical sheaths seems to be associated with a lower incidence of VA/T. A strategy of pericardiocentesis followed by a rescue surgical approach seems to be reasonable in order to treat a CA/T with tamponade.

Keywords Lead extraction • Major complications • Cardiac tamponade • Registry

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† A complete list of the ELECTRa Investigators is provided in the Supplementary material online, Appendix S1.

What's new?

- RIATA lead extraction is a major determinant of cardiac avulsion or tear (CA/T) with tamponade, whereas patients with heart failure seem to have less likelihood to have such a complication.
- Occlusion or critical stenosis of superior venous access (subclavian, innominate veins, and superior vena cava) is an independent predictor for major vascular complications but not for cardiac tamponade.
- Mechanical dilation was associated with a lower incidence of vascular complications during transvenous lead extraction as compared to the use of powered sheaths.
- A strategy of pericardiocentesis followed by a rescue surgical approach seems to be reasonable in order to treat a CA/T with tamponade.

Introduction

Transvenous lead extraction (TLE) is nowadays a safe and effective procedure, allowing for the management of most cardiac implantable electronic device (CIED) complications.[1] However, life-threatening complications still occur, and several attempts have been made to identify subgroups of population or procedural features that could predict major adverse events.[2,3] Vascular avulsion or tear (VA/T) due to superior vena cava laceration and cardiac avulsion or tear (CA/T) with tamponade are the most frightening complications.[4] The former one is a catastrophic event, rarely seen in centre using mechanical sheaths[5,6] and the latter, which is more common than superior vena cava laceration, occurs equally in centres using both powered or mechanical sheaths.[7] The European Lead Extraction ConTRolled (ELECTRa) study recently shed some light on the current clinical practice of TLE. Importantly, this registry confirmed that TLE with mechanical (not powered) sheath still remains the most used technique in Europe, thus emphasizing the pivotal role of CA/T with tamponade among all the major complications in conditioning a safety outcome.[2] The aims of this ancillary study were to describe outcomes and identify predictors of major cardiac and vascular complications (CA/T with tamponade and VA/T) in the ELECTRa study.

Methods

The design, baseline characteristics and results from the ELECTRa study have been previously published.[7] The executive committee in cooperation with the EURObservational Research Programme (EORP) provided the study design, protocol, and the scientific leadership of the registry under the responsibility of the European Heart Rhythm Association (EHRA) Scientific Initiatives Committee. In brief, the ELECTRa study is a prospective registry with the aim of identifying the safety and efficacy of the current clinical practice of TLE in Europe. A total of 3555 consecutive patients of whom 3510 underwent TLE at 73 centres in 19 European countries were enrolled between November 2012 and May 2014. For this ancillary analysis, we evaluated outcomes and predictors of CA/T with tamponade and VA/T.

Definitions

Definitions published in the consensus report from Heart Rhythm society in 2009[8] and by EHRA in 2012[9] were used to define procedural approach, techniques, and outcomes. Major complications were defined as those related to the procedure that were life-threatening or resulted in death, or any unexpected event that caused persistent or significant disability, or any event that required significant surgical intervention to prevent any of outcomes listed above. The complications were classified by the physician as being procedure-related or not; intra-procedural complications were defined as any event related to the procedure that occurred from the time the patient entered the operating room or the electrophysiology laboratories (EP labs) until the time he left the room. Post-procedural complications were defined as any other such event occurring after the procedure until patient discharge. In this ancillary analysis, we defined CA/T complicated by tamponade as any pericardial effusion that required pericardiocentesis, pig tail positioning or surgical repair and attributed by the investigator to be a cardiac laceration, whereas VA/T was defined as any major complication suspected to be derive from a laceration of a thoracic vein. The attribution of major cardiovascular (CV) complication to a cardiac or a venous laceration was established by the local ELECTRa investigator at the time of the case report form filling.

Statistical analysis

Continuous variables were expressed as mean ± SD or as median and interquartile range. Among-group comparisons were made using a non-parametric test (the Kruskal–Wallis test). Categorical variables were reported as counts and percentages. Among-group comparisons were made using a χ^2 test or the Fisher's exact test (if any expected cell count was less than five). Following simple logistic regressions, a stepwise multiple regression algorithm was used to determine the predictors of CA/T leading to tamponade, and VA/T including into the models all the candidate variables (variables with $P < 0.05$ in univariate, except those with more than 20% of missing data, and variables considered of relevant clinical interest), which were predefined in the protocol. A significance level of 0.05 was required to allow a variable into the model (SLENTRY = 0.05), and a significance level of 0.05 was required for a variable to remain in the model (SLSTAY = 0.05). No interaction was tested. A Hosmer and Lemeshow Goodness-of-Fit test was used to verify that the model was optimal. Receiver operating curves were derived to assess the predictive value of mean and maximum dwelling time of the leads for C leading to tamponade. A two-sided *P*-value of 0.05 was considered as statistically significant. All the analyses were performed using SAS statistical software version 9.4 (SAS Institute, Inc., Cary, NC, USA).

Results

Characteristics of population study and transvenous lead extraction procedures

The in-hospital major complications, divided in intra-procedural and post-procedural complications, and in CA/T and VA/T are represented in *Figure 1*. In particular, CV avulsion or tear was the main cause of in-hospital procedure-related major complication (49/58; 84.5%), and CA/T complicated by tamponade was the most frequent cause of major CV events (30/49; 61.2%). The main baseline characteristics of patients according with principal major CV complications compared with global population and patients without major CV complications are represented in *Table 1*. Cardiovascular complications were more often observed in female gender ($P = 0.0082$), thrombosis or stenosis of superior venous axis ($P = 0.0087$), longer

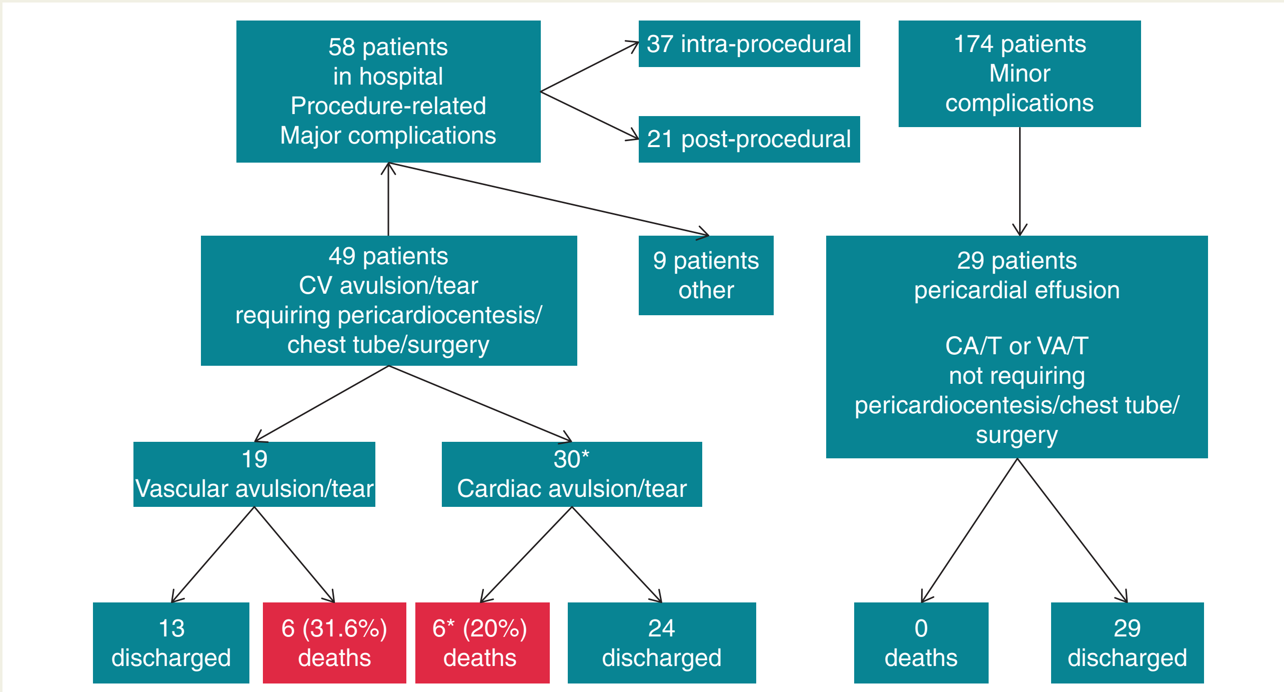

Figure 1 On the left, in-hospital major complications, divided in intra-procedural and post-procedural ones, and in cardiac avulsion or tear (CA/T) and vascular avulsion or tear (VA/T). On the right, minor complications, with focus on CA/T or VA/T with pericardial effusion not requiring pericardiocentesis/chest tube positioning or surgery. *Two patients with both vascular and cardiac avulsion/tear. CV, cardiovascular.

median dwelling time ($P < 0.0001$), passive fixation ($P = 0.0226$), and unipolar leads ($P < 0.0001$; only for CA/T with tamponade). Patients with heart failure were more frequently observed in the group without major CV complication than in CA/T and VA/T groups (CA/T vs. VA/T vs. no CV complications: 16.67% vs. 31.58% vs. 44.95%; $P = 0.0041$). The procedural characteristics according with principal major CV complications, and compared with global population and patients without major CV complications are represented in *Table 2*. Major CV complications were mainly observed in case of TLE under general anaesthesia, with cardiothoracic surgeon present in the room, and approaching more leads compared with global population and patients without major CV complications. All the procedures complicated by VA/T were performed by a cardiologist as primary operator and more than half (52.63%) happened in a EP lab. Procedure, extraction and fluoroscopy time as well as duration of hospital stay were higher in the complicated patients, in whom rarely a manual traction was used; mechanical sheaths were rarely used in patients with VA/T (12.20%), in whom the extraction with powered sheaths was frequent (63.41%). The calibre of sheaths was larger in patients with CA/T with tamponade (CA/T vs. VA/T vs. no CV complications: 15.20 vs. 14.00 vs. 13.90; $P = 0.0001$), and even the total number of sheaths was higher in CA/T group compared with the other groups (CA/T vs. VA/T vs. no CV complications: 2 vs. 1 vs. 1; $P = 0.0009$). Femoral approach was frequent in patients with VA/T (CA/T vs. VA/T vs. no CV complications: 1.52% vs. 9.76% vs. 4.74%; $P < 0.0001$), whereas the use of jugular approach, even when it was combined with the femoral one, was never described in procedures complicated by major vascular complications.

Acute outcomes and predictors of cardiac avulsion or tear and vascular avulsion or tear

The radiological complete success rate was 83.33% in CA/T with tamponade, 85.37% in VA/T, and 95.87% in patients without major CV complications ($P < 0.0001$). The mortality after TLE was higher in VA/T compared with CA/T with tamponade and patients without major complications (31.58% vs. 20% vs. 0.14%; $P < 0.0001$) (*Figure 1*). Only 20% (6/30; 1 death) of tamponade due to CA/T was labelled as post-procedural, whereas 42.11% (8/19; 2 deaths) of VA/T were included in the post-procedural complications (*Table 3*). A mean and max dwelling time more than 10 years, an extraction of a Saint Jude RIATA lead, the total number of sheaths used and the presence of the surgeon in the room were all associated at univariate analysis with a higher likelihood of CA/T with tamponade after TLE, whereas the male gender and heart failure were both associated with lower incidence of that complication. In *Figure 2*, the only covariates that remained predictors of CA/T with tamponade at multivariate analysis were the mean leads dwelling time more than 10 years (OR 5.13, 95% CI 2.25–11.68; $P = 0.0001$), the extraction of a RIATA lead (OR 4.12, 95% CI 1.29–13.16; $P = 0.0168$), the extraction of three leads or more (OR 3.02, 95% CI 1.29–7.05; $P = 0.0107$), and the total number of sheaths used during TLE procedure (OR 1.66, 95% CI 1.33–2.08; $P < 0.0001$). Male patients (OR 0.38, 95% CI 0.18–0.83; $P = 0.0148$) and patients with chronic heart failure (OR 0.29, 95% CI 0.1–0.82; $P = 0.0197$) had a lower likelihood of CA/T with tamponade, even at multivariate analysis. Receiver operator curves revealed the mean and maximum dwelling time of leads extracted of 11 years [area

Table 1 Baseline characteristics of patients according with principal major cardiovascular complications

	Total (*N* = 3510)	CA/T requiring p/c/s (*N* = 30)	VA/T requiring p/c/s (*N* = 19)	No CV major complications (*N* = 3461)	*P*-value
Age (years)	64.88 ± 15.62	61.07 ± 18.44	62.58 ± 15.28	64.93 ± 15.60	0.5494
Male	2539/3510 (72.34%)	15/30 (50%)	11/19 (57.89%)	2513/3461 (72.61%)	0.0082
BMI (kg/m^2)	26.10 [23.50–29.30]	26.00 [25.00–27.90]	25.30 [22.80–28.30]	26.10 [23.50–29.30]	0.5333
Clinical data/co-morbidities					
Diabetes	781/3487 (22.40%)	5/30 (16.67%)	2/19 (10.53%)	774/3438 (22.51%)	0.3440
Hypertension	1888/3478 (54.28%)	12/30 (40.00%)	10/19 (52.63%)	1866/3429 (54.42%)	0.2847
Coronary artery disease	1375/3482 (39.49%)	10/30 (33.33%)	5/18 (27.78%)	1360/3434 (39.60%)	0.4658
Valvular heart disease	514/3500 (14.69%)	4/30 (13.33%)	3/19 (15.79%)	507/3451 (14.69%)	0.9693
Previous sternotomy	596/3504 (17.01%)	2/30 (6.67%)	2/19 (10.53%)	592/3455 (17.13%)	0.2372
Chronic heart failure	1557/3488 (44.64%)	5/30 (16.67%)	6/19 (31.58%)	1546/3439 (44.95%)	0.0041
Chronic kidney disease	613/3493 (17.55%)	5/29 (17.24%)	2/19 (10.53%)	606/3445 (17.59%)	0.7212
COPD	297/3483 (8.53%)	1/28 (3.57%)	0/19 (0.00%)	296/3436 (8.61%)	0.2609
Indication					
Infections	1865/3499 (53.30%)	15/30 (50.00%)	10/19 (52.63%)	1840/3450 (53.33%)	0.9341
Local	1170/3499 (33.44%)	8/30 (26.67%)	5/19 (26.32%)	1157/3450 (33.54%)	0.5868
Systemic	680/3499 (19.43%)	7/30 (23.33%)	5/19 (26.32%)	668/3450 (19.36%)	0.6448
No infection	1645/3510 (46.87%)	15/30 (50.00%)	9/19 (47.37%)	1621/3461 (46.84%)	0.9410
Thrombosis or venous stenosis and/or signs/symptoms of venous occlusion	223/3510 (6.35%)	4/30 (13.33%)	4/19 (21.05%)	215/3461 (6.21%)	0.0087
CIED history (type of device)					
Right sided	654/3510 (18.63%)	8/30 (26.67%)	7/19 (36.84%)	639/3461 (18.46%)	0.0639
Pacemaker dependent	778/3510 (22.17%)	11/30 (36.67%)	7/19 (36.84%)	760/3461 (21.96%)	0.0470
Pacemakers	1848/3510 (52.65%)	20/30 (66.67%)	12/19 (63.16%)	1816/3461 (52.47%)	0.1968
Single chamber	354/1848 (19.16%)	4/20 (20.00%)	1/12 (8.33%)	349/1816 (19.22%)	0.3105
Dual chamber	1333/1848 (72.13%)	15/20 (75.00%)	10/12 (83.33%)	1308/1816 (72.03%)	
CRT-P	127/1848 (6.87%)	0/30 (0.00%)	0/19 (0.00%)	127/1816 (6.99%)	
Other	34/1848 (1.84%)	1/20 (5.00%)	1/12 (8.33%)	32/1816 (1.76%)	
ICD	1655/3510 (47.15%)	10/30 (33.33%)	7/19 (36.84%)	1638/3461 (47.33%)	0.2067
Single chamber	467/1655 (28.22%)	1/10 (10.00%)	3/7 (42.86%)	463/1638 (28.27%)	0.5934
Dual chamber	577/1655 (34.86%)	6/10 (60.00%)	1/7 (14.29%)	570/1638 (34.80%)	
CRT-D	606/1655 (36.62%)	3/10 (30.00%)	3/7 (42.86%)	600/1638 (36.63%)	
Other	5/1655 (0.30%)	0/30 (0.00%)	0/19 (0.00%)	5/1638 (0.31%)	
CIED history (type of leads)					
Lead extracted ≥ 3	697/3510 (19.86%)	10/30 (33.33%)	5/19 (26.32%)	682/3461 (19.71%)	0.1372
Pacing leads	4584/6493 (70.60%)	52/66 (78.79%)	32/41 (78.05%)	4500/6386 (70.47%)	0.1937
Bipolar	4147/4584 (90.47%)	36/52 (69.23%)	32/32 (100.00%)	4079/4500 (90.64%)	<0.0001
Unipolar	388/4584 (8.46%)	16/52 (30.77%)	0/41 (0.00%)	372/4500 (8.27%)	
Tripolar	18/4584 (0.39%)	0/66 (0.00%)	0/41 (0.00%)	18/4500 (0.40%)	
Quadripolar	31/4584 (0.68%)	0/66 (0.00%)	0/41 (0.00%)	31/4500 (0.69%)	
ICD leads	1909/6493 (29.40%)	14/66 (21.21%)	9/41 (21.95%)	1886/6386 (29.53%)	0.1937
Dual coils	996/1909 (52.17%)	11/14 (78.57%)	3/9 (33.33%)	982/1886 (52.07%)	0.0743
Fixation type (active)	3381/6333 (53.39%)	27/59 (45.76%)	14/41 (34.15%)	3340/6233 (53.59%)	0.0226
Dwelling time	5 [2–9]	12 [6–19]	9 [5–13]	5 [2–8]	<0.0001
Previous attempt of TLE	171/3510 (4.87%)	4/30 (13.33%)	0/19 (0.00%)	167/3461 (4.83%)	0.0600
Investigations before TLE					
TTE assessment	2774/3510 (79.03%)	21/30 (70.00%)	16/19 (84.21%)	2737/3461 (79.08%)	0.4087
TOE assessment	1608/3510 (45.81%)	16/30 (53.33%)	10/19 (52.63%)	1582/3461 (45.71%)	0.5902
Vegetation	497/1608 (30.91%)	5/16 (31.25%)	3/10 (30.00%)	489/1582 (30.91%)	0.9976
Laboratory test pre-extraction					
C-reactive protein (mg/L)	3.6 [1–12]	4.15 [1.8–12.2]	4.50 [2.7–38.5]	3.56 [1–12]	0.4048
Preoperative treatment					
Anticoagulation	1302/3510 (37.09%)	7/30 (23.33%)	7/19 (36.84%)	1288/3461 (37.21%)	0.2927
Bridging	504/1302 (38.71%)	4/7 (57.14%)	1/7 (14.29%)	499/1288 (38.74%)	0.2511

Continued

Table 1 *Continued*

	Total (*N* = 3510)	CA/T requiring p/c/s (*N* = 30)	VA/T requiring p/c/s (*N* = 19)	No CV major complications (*N* = 3461)	*P*-value
Anti-platelets	1413/3510 (40.26%)	11/30 (36.67%)	6/19 (31.58%)	1396/3461 (40.34%)	0.6823
Interrupted	1035/1413 (73.25%)	8/11 (72.73%)	5/6 (83.33%)	1022/1396 (73.21%)	0.8546
Antibiotics	1923/3510 (54.79%)	19/30 (63.33%)	10/19 (52.63%)	1894/3461 (54.72%)	0.6294
Time since start (days)	10 [5–20]	10 [5–22]	15 [5–20]	10 [5–20]	0.9176

BMI, body mass index; CA/T, cardiac avulsion or tear; CIED, cardiac implantable electronic device; COPD, chronic pulmonary disease; CRT-D, cardiac resynchronization therapy-defibrillator; CRT-P, cardiac resynchronization therapy-pacemaker; CV, cardiovascular major complications; d, days; ICD, implantable cardioverter-defibrillator; p/c/s pericardiocentesis/chest tube/surgical procedure; TLE, transvenous lead extraction; TOE, transoesophageal echocardiography; TTE, transthoracic echocardiography; VA/T, vascular avulsion or tear.

Table 2 **Procedure characteristics of patients according with principal major cardiovascular complications**

	Total (*N* = 3510)	CA/T requiring p/c/s (*N* = 30)	VA/T requiring p/c/s (*N* = 19)	No CV major complications (*N* = 3461)	*P*-value
Procedural room					
Operating room	1824/3510 (51.97%)	19/30 (63.33%)	7/19 (36.84%)	1798/3461 (51.95%)	0.4501
EP-Lab	1351/3510 (38.49%)	8/30 (26.67%)	10/19 (52.63%)	1333/3461 (38.51%)	
Hybrid	335/3510 (9.54%)	3/30 (10%)	2/19 (10.53%)	330/3461 (9.53%)	
Anaesthesia					
Local	1073/3510 (30.57%)	7/30 (23.33%)	0/19 (0%)	1066/3461 (30.80%)	0.0052
Sedation	1077/3510 (30.68%)	7/30 (23.33%)	5/19 (26.32%)	1065/3461 (30.77%)	
General	1360/3510 (38.75%)	16/30 (53.33%)	14/19 (73.68%)	1330/3461 (38.43%)	
High-volume centre	2882/3510 (82.11%)	24/30 (80%)	13/19 (68.42%)	2845/3461 (82.2%)	0.2816
Primary operator Cardiologist	3181/3510 (90.63%)	28/30 (93.33%)	19/19 (100%)	3134/3461 (90.55%)	0.6194
Cardiothoracic surgeon	258/3510 (7.35%)	2/30 (6.67%)	0/19 (0%)	256/3461 (7.4%)	
CT Surgeon present in the room	565/3510 (16.1%)	9/30 (30%)	11/19 (57.89%)	545/3461 (15.75%)	<0.0001
Lead extracted	2.26 ± 0.96	2.52 ± 0.83	2.66 ± 1.20	2.25 ± 0.95	0.0039
Saint Jude RIATA	237/6495 (3.65%)	6/66 (9.09%)	1/41 (2.44%)	230/6388 (3.6%)	0.0557
Saint Jude DURATA	176/6495 (2.71%)	1/66 (1.52%)	0/41 (0%)	175/6388 (2.74%)	0.4675
Procedure time (min)	83.00 [57–120]	185.00 [120–255]	123.00 [60–210]	80.00 [57–120]	<0.0001
Extraction time (min)	19 [6–40]	60 [25–109]	30 [16–70]	19 [5–38]	<0.0001
Fluoroscopy time (min)	9 [4–17]	25 [9.43–41]	13.8 [8–25]	8.51 [4–17]	<0.0001
Duration of hospital stay related to TLE (days)	5 [3–8]	11 [7–23]	7 [2–20]	4 [3–8]	0.0002
Lead removed with traction alone	1741/6376 (27.31%)	4/66 (6.06%)	6/39 (15.38%)	1731/6271 (27.60%)	0.0001
Locking stylets	4360/6493 (67.15%)	47/66 (71.21%)	34/41 (82.93%)	4279/6386 (67.01%)	0.0750
Sheaths used	4127/6492 (63.57%)	48/66 (72.73%)	31/41 (75.61%)	4048/6385 (63.40%)	0.0805
Mechanical sheaths	2359/6492 (36.34%)	27/66 (40.91%)	5/41 (12.20%)	2327/6385 (36.44%)	0.0041
Powered sheaths	1757/6492 (27.06%)	21/66 (31.82%)	26/41 (63.41%)	1710/6385 (26.78%)	<0.0001
Laser sheaths	1250/6492 (19.25%)	17/66 (25.76%)	16/41 (39.02%)	1217/6385 (19.06%)	0.0021
Evolution sheaths	500/6492 (7.70%)	4/66 (6.06%)	10/41 (24.39%)	486/6385 (7.61%)	0.0002
EDS sheaths	7/6492 (0.11%)	0/66 (0%)	0/41 (0%)	7/6385 (0.11%)	0.9429
Other	11/6492 (0.17%)	0/66 (0%)	0/41 (0%)	11/6385 (0.17%)	0.9118
Maximum sheaths used	13.90 [11.00–15.20]	15.2 [13–16]	14 [11–16]	13.9 [11–15]	0.0001
Total number of sheaths used	1 [1–2]	2 [1–3]	1 [1–2]	1 [1–2]	0.0009
Alternative approach					
Femoral	308/6492 (4.74%)	1/66 (1.52%)	4/41 (9.76%)	303/6385 (4.75%)	<0.0001
Jugular	44/6492 (0.68%)	0/66 (0%)	0/41 (0%)	44/6385 (0.69%)	
Jugular and femoral	19/6492 (0.29%)	4/66 (6.06%)	0/41 (0%)	15/6385 (0.23%)	
Other	30/6492 (0.46%)	1/66 (1.52%)	2/41 (4.88%)	27/6385 (0.42%)	

CA/T, cardiac avulsion or tear; CT, cardiothoracic; CV, cardiovascular major complications; EDS, electrosurgical dissection; EP, electrophysiology; p/c/s, pericardiocentesis/chest tube/surgical procedure; TLE, transvenous extraction; VA/T, vascular avulsion or tear.

Table 3 Acute outcome according with principal major cardiovascular complications

	Total (*N* = 3510)	CA/T requiring p/c/s (*N* = 30)	VA/T requiring p/c/s (*N* = 19)	No CV major complications (*N* = 3461)	*P*-value
Radiological outcome-complete	6212/6493 (95.67%)	55/66 (83.33%)	35/41 (85.37%)	6122/6386 (95.87%)	<0.0001
Procedure-related major complications including deaths	58/3510 (1.65%)	30/30 (100.00%)	19/19 (100.00%)	9/3461 (0.26%)	<0.0001
Intraprocedural	37/3510 (1.05%)	24/30 (80.00%)	11/19 (57.89%)	2/3461 (0.06%)	<0.0001
Post-procedural	21/3510 (0.60%)	6/30 (20.00%)	8/19 (42.11%)	7/3461 (0.20%)	<0.0001
Procedure-related deaths	17/3510 (0.48%)	6/30 (20.00%)	6/19 (31.58%)	5/3461 (0.14%)	<0.0001
Intraprocedural	9/3510 (0.26%)	5/30 (16.67%)	4/19 (21.05%)	0/3461 (0.00%)	<0.0001
Post-procedural	8/3510 (0.23%)	1/30 (3.33%)	2/19 (10.53%)	5/3461 (0.14%)	<0.0001
CIED implanted during hospital stay	2379/3510 (67.78%)	18/30 (60.00%)	11/19 (57.89%)	2350/3461 (67.90%)	0.4265
CIED not implanted during hospital stay	1131/3510 (32.22%)	12/30 (40.00%)	8/19 (42.11%)	1111/3461 (32.10%)	0.4265
If not implanted, absence of indication	311/1131 (27.50%)	1/12 (8.33%)	0/19 (0.00%)	310/1111 (27.90%)	0.0693
If not implanted, delayed	559/1131 (49.43%)	3/12 (25.00%)	2/8 (25.00%)	554/1111 (49.86%)	0.0880
If not implanted, death before reimplantation	24/3510 (0.68%)	4/30 (13.33%)	4/19 (21.05%)	16/3461 (0.46%)	<0.0001
Time extraction to reimplantation (days)	3.18 ± 8.46	4.11 ± 9.88	4.09 ± 7.52	3.17 ± 8.45	0.5869
Complication during reimplantation	100/2379 (4.20%)	3/18 (16.67%)	1/11 (9.09%)	96/2350 (4.09%)	0.0215

CA/T, cardiac avulsion or tear; CIED, cardiac implantable electronic device; CV, cardiovascular major complications; p/c/s, pericardiocentesis/chest tube/surgical procedure; VA/T, vascular avulsion or tear.

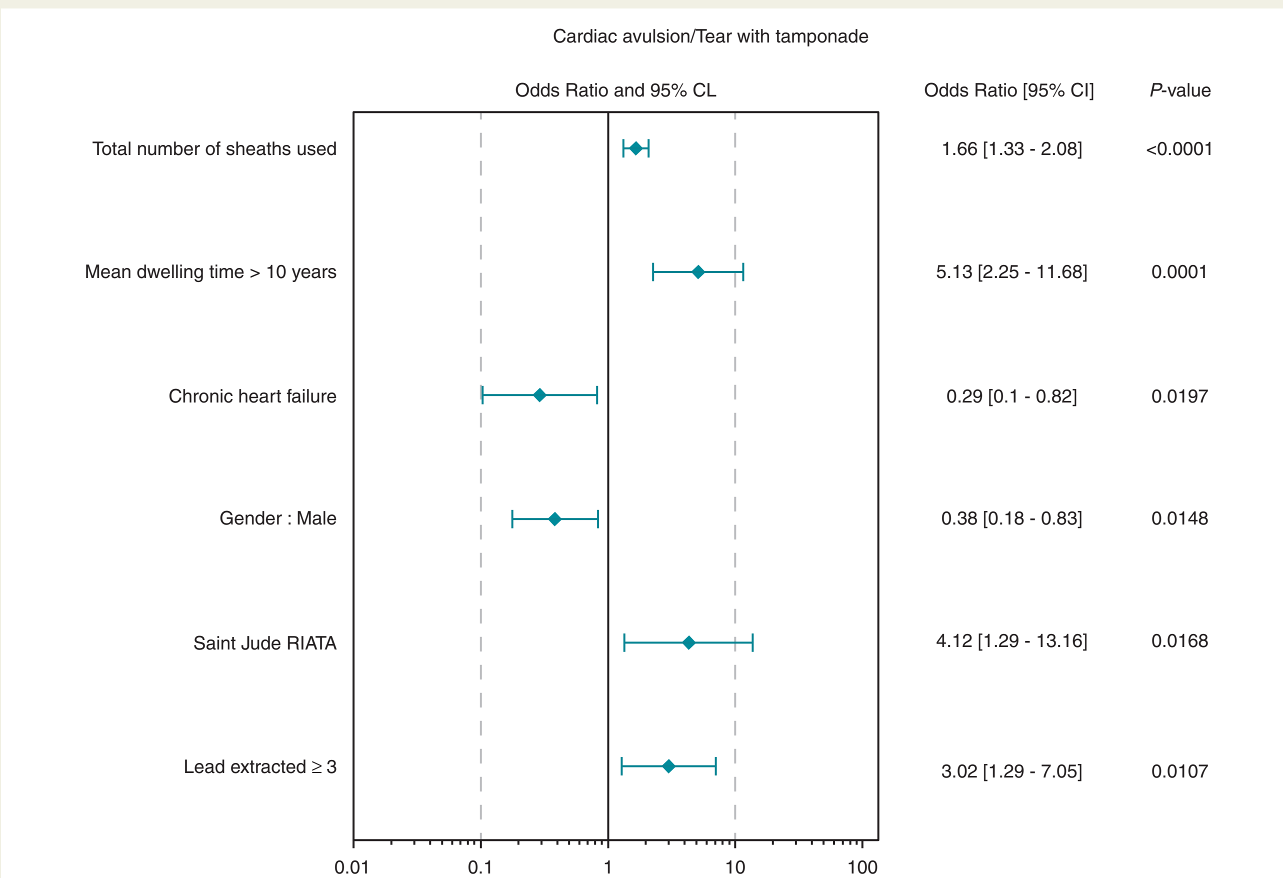

Figure 2 Predictors of cardiac avulsion or tear with tamponade. CI, confidence interval.

under curve (AUC) = 0.75; sensitivity 0.567, specificity 0.845, negative predictive value 0.996], and 14 years (AUC = 0.75; sensitivity 0.5, specificity 0.886, negative predictive value 0.995) as the best predictors of tamponade due to CA/T. Occlusion or critical stenosis of superior venous access, right sided implant, a mean and max leads dwelling time more than 10 years, the extraction of three leads or more, and the femoral approach were all associated at univariate analysis with a higher likelihood of VA/T after TLE, whereas exclusive use of mechanical sheaths during TLE was associated with lower incidence of this complication. At multivariate analysis, the only factors that still remained predictors of VA/T were the occlusion or critical stenosis of superior venous axis (OR 5.74, 95% CI 1.71–19.22; $P = 0.0046$), and the mean leads dwelling time more than 10 years (OR 3.19, 95% CI 1.21–8.40; $P = 0.0187$), whereas the exclusive use of mechanical sheaths during TLE was associated with a lower likelihood of VA/T compared with powered sheaths (OR 0.12, 95% CI 0.03–0.52; $P = 0.0051$) (*Figure 3*).

Management of cardiac avulsion or tear with tamponade and predictors of fatal cardiac avulsion or tear

Sixteen out of 30 patients (30%) with CA/T complicated by tamponade underwent pericardiocentesis, that succeeded in 10/16 patients (62.5%), while in the remaining 6/16 patients the pericardiocentesis was followed by sternotomy or thoracotomy (in one case without surgical repair), that succeed in 5/6 patients (83.3%); the approach including pericardiocentesis as first manoeuvre followed by sternotomy with surgical repair as rescue was successful in 15/16 patients (93.8%). In 14/30 patients (46.7%) a sternotomy/thoracotomy was performed as first approach to treat tamponade and was successful in 64.3% (9/14). The sternotomy/thoracotomy were followed by a surgical repair in 6/14 patients (42.85%) and succeeded in 2/6 patients (33.33%). Seven out of the eight patients (87.50%) who had undergone sternotomy/thoracotomy without surgical repair (only drainage after surgical access) were alive at discharge (*Figure 4*). Patients in whom an attempt of pericardiocentesis had been performed at the beginning of the tamponade were basically younger compared with those who had been directly treated with a sternotomy/thoracotomy (55.88 ± 20.21 vs. 67 ± 14.68 years; $P = 0.0999$). The former approach had been performed in 87.5% of the CA/T occurred in the EP-lab as compared to 47.37% and 33.33% occurred in the operating room and hybrid room, respectively ($P = 0.0744$). All six patients with fatal CA/T had undergone TLE in the operating room, in 3/6 patients the surgeon was not immediately available at the time of the complication and in 3/6 cases it occurred in a low volume centre; locking stylet with powered sheaths were used in 3/6 cases, a standard stylet with mechanical sheaths in 2/6 cases, only locking stylet in 1/6 cases. Patients with fatal CA/T were older (fatal CA/T 70.83 ± 8.35 vs. no-fatal CA/T 58.63 ± 19.55 years; $P = 0.0307$) and underwent TLE more frequently in low-volume centres (fatal CA/T 50% vs. no-fatal CA/T 12.5%; $P = 0.04$) as compared to survivors, who had usually been treated with a strategy of pericardiocentesis followed by a surgical approach as rescue (no-fatal CA/T 62.5% vs. fatal CA/T 16.67%;

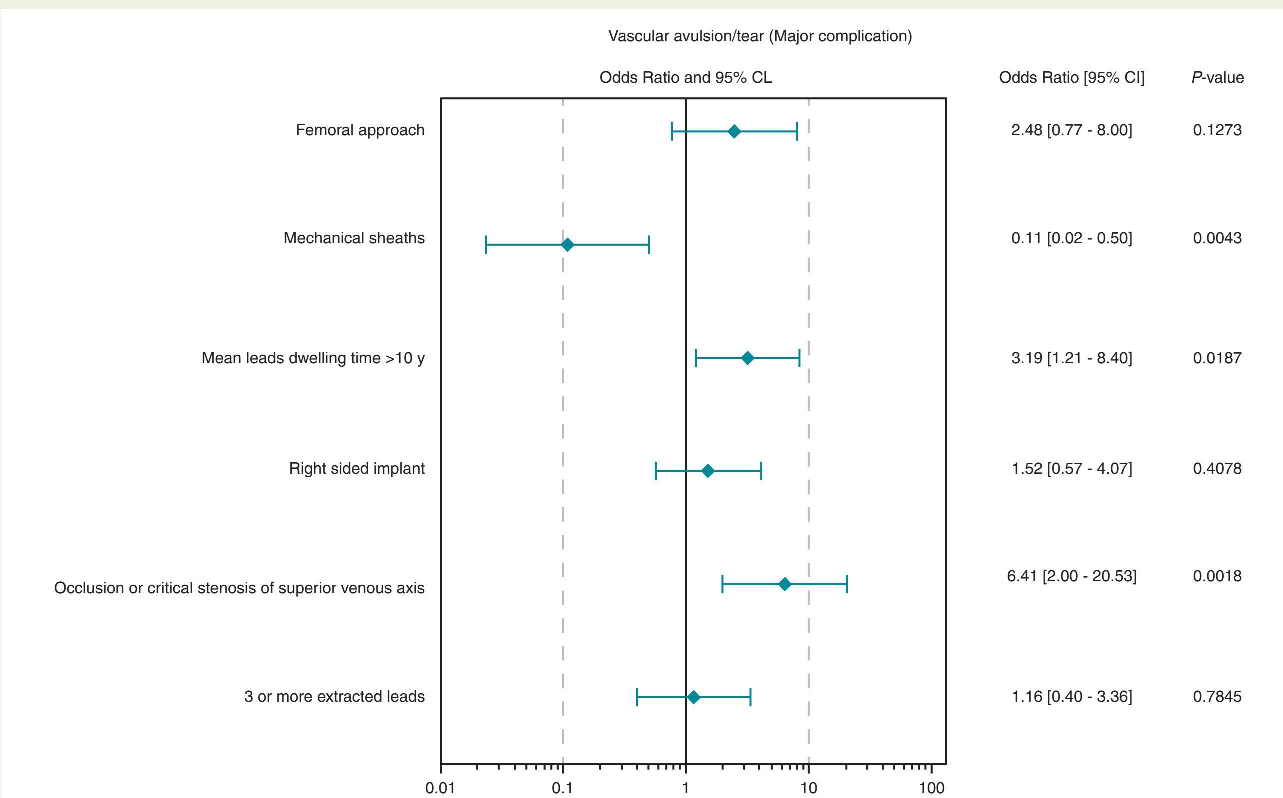

Figure 3 Predictors of vascular avulsion or tear as major complication. CI, confidence interval.

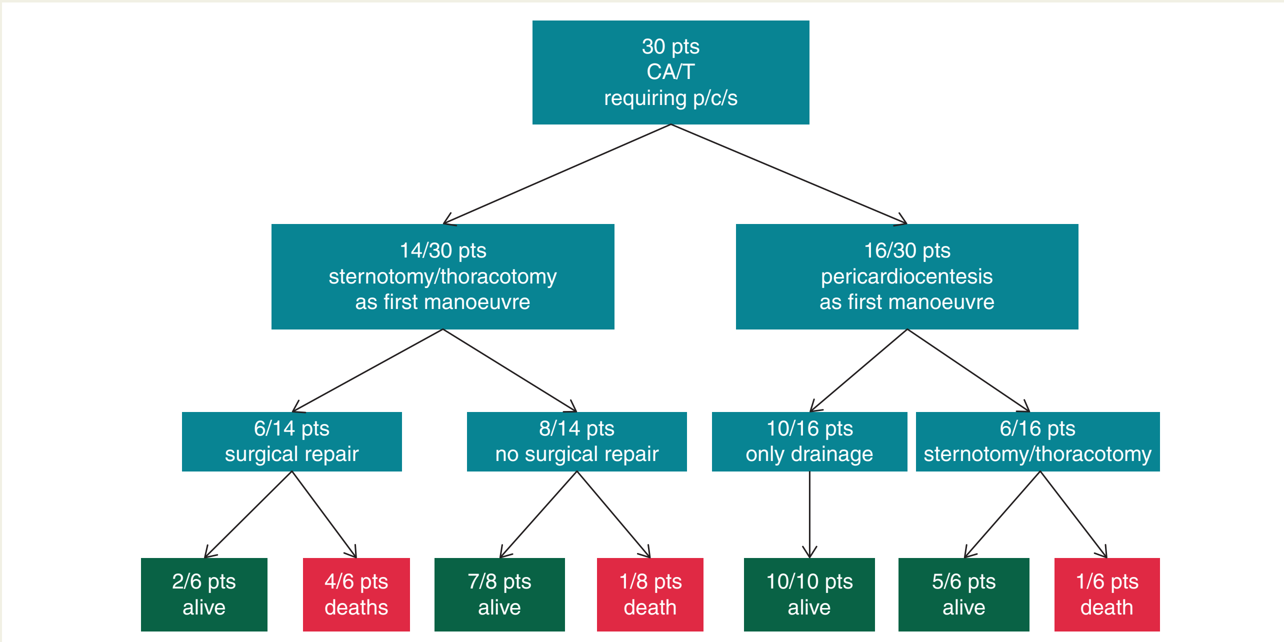

Figure 4 Flow-chart of cardiac tamponade management in patients with cardiac avulsion or tear. CA/T, cardiac avulsion or tear; p/c/s, pericardiocentesis/chest tube/surgical procedure.

P = 0.0441). At univariate and multivariate analysis, there were no predictors of fatal CA/T.

Discussion

The major findings of this ancillary study were: (i) CA/T with tamponade was the most frequent major CV complication after TLE in ELECTRa registry, but not the most dangerous. In fact, mortality in patients with tamponade due to CA/T was 20%, whereas increased up to 31.6% after a VA/T; (ii) we found two new predictors for cardiac tamponade due to CA/T (RIATA lead extraction) and for VA/T (occlusion or critical stenosis of superior venous axis); (iii) pericardiocentesis as first manoeuvre to treat a cardiac tamponade due to CA/T, followed by sternotomy with surgical repair as rescue, was highly effective (93.8%); and (iv) TLE using mechanical sheaths and the jugular approach were rarely associated with vascular complications.

Major cardiovascular complications: relationship with pre-procedural characteristics, transvenous lead extraction approaches, and techniques

The identification of CA/T and VA/T predictors has a pivotal role in the proper management of patients undergoing TLE. In a recent study, the authors found that patients with venous access occlusion usually required longer procedural duration, fluoroscopy exposure time, and more advanced tools for lead extraction.[10] We found an association between a significant venous obstruction or thrombosis and VA/T; pre-procedural venography before TLE could therefore identify patients at risk of such complications. We found that the only factor that could reduce the incidence of VA/T was the use of mechanical sheaths and for this reason, in case of venous access issue, their use should be taken into account, even though we could expect a longer duration of the procedure. On the other hand, if the operator decides to perform a procedure with powered sheaths in presence of venous issues along the leads course, a proper TLE location (i.e. operating room) with cardiothoracic surgeon as primary operator or at least scrubbed in the room, or a prophylactic use of an endovascular balloon have to be considered.[11] A higher presence of surgeon in the room and use of general anaesthesia in patients with major CV complications, as well as the absence of fatal cardiac tamponade due to CA/T in EP-lab may be explained by a proper evaluation of pre-operative risk, taking into account known predictive factors for catastrophic complications (female sex, lead dwelling time, number of leads . . .). In other terms, challenging TLE in fragile patients were usually located in the operating room. The female gender, lead dwelling time, and the need for extraction more than three leads were major determinants for CA/T with tamponade; these data are in line with those from other mono- and multicentre studies.[2,3,12] While the risk of female gender is partially determined by associated low body mass index and a higher frailty of this subgroup compared with males, the other predictive factors (long lead dwelling time; more than three leads requiring TLE) are specific markers of challenging procedure due to the high likelihood to develop tight adherences along the leads course, especially in implantable cardioverter-defibrillator (ICD) leads.[13–15] The lower incidence of CA/T with tamponade in patients with heart failure could be related with the presence of right ventricular hypertrophy associated with high pulmonary pressure found in these patients.

The extraction of a RIATA lead predicts cardiac tamponade due to CA/T, but is not associated with an increased risk of total major complications, major CV complications, or VA/T. The RIATA lead is a known predictive factor of more challenging TLE procedures and, in case of mechanical dilation, it often requires larger sheaths, longer procedure time, and the need for complex approaches (i.e. jugular approach).[16] The lack of coil backfilling and cable externalization may account for the fact that these leads are more complex to extract than other recalled ICD leads. The risk of cardiac tear seems to represent the Achille's heels of these leads. For this reason, the abandonment may represent the treatment of choice instead of TLE, especially in case of long dwelling time and no infective indications.[17,18]

Management of cardiac tamponade due to cardiac avulsion or tear

No deaths were observed in EP lab, while in a previous study from a high-volume centre, the cardiac tamponade-related mortality rate was 37% when TLE was performed in an EP lab.[6] This should be properly interpreted and could suggest again that in the ELECTRa registry the investigators adequately referred high risk patients to the operating theatre. In case of surgical repair after primary thoracotomy/sternotomy the survival was low (33.33%), even though these cases were all performed in the operating room. Nevertheless, the surgeon was not immediately available at time of complication in 3/6 fatal cases. The overall mortality (30%) after urgent cardiac surgery following a CA/T with tamponade in ELECTRa registry was comparable with recent data from an American registry.[7]

We can suppose that a strategy of pericardiocentesis followed by a surgical approach as rescue could be reasonable in order to treat a cardiac tamponade due to CA/T, especially in case of procedure performed in the EP lab, due to the high success rate (93.8%) in ELECTRa study. On the other hand, in case of procedure scheduled in the operating room, a delay in chest opening due to the absence of surgeon in the room is not acceptable and could explain some fatal cases after primary sternotomy. Finally, the treatment of CA/T with tamponade in a high-volume centre could be associated with a lower incidence of fatal events compared with low-volume centres, thus underlying the need to perform TLE procedures in a proper setting with expert operators.

Limitations

Limitations of the observational studies could influence the findings of this ancillary analysis. Particularly, the registry is based with voluntary participation of the centres involved, therefore leading to a substantial risk of inclusion bias and a potential impact of complication rates estimation. The identification of predictors of outcome was not in the purpose of ELECTRa registry and the study was not powered for this aim. In line with a recently published single-centre experience, the attribution of cardiac tamponade to either CA/T or VA/T may be difficult and may require the use of specific imaging diagnostics such as intra-procedural transoesophageal echocardiography.[19] Moreover, the group with VA/T actually included not only thoracic vein lacerations but also one case of femoral tear and one case of bleeding during abdominal pacemaker reimplantation, and for this reason we cannot translate VA/T results as outcomes limited only to the lacerations of thoracic veins. The association of VA/T and CA/T in two patients could have influenced the results in terms of outcomes and predictors. The results achieved by using the jugular approach were obtained by experienced and skilled operators and could not be reproduced in low-volume centres; for this reason, a wider use of this technique is desirable before drawing general conclusions. On the other hand, we cannot exclude an excess of challenging cases treated with powered sheaths that could represent a potential bias in the outcome analysis on vascular complications. Anyway, this ancillary analysis gives us an overview of treatment strategy and acute outcome of major CV complications, suggesting relationships with pre- and intraprocedural features that should be confirmed by randomized and controlled study.

Conclusions

This ancillary analysis from the ELECTRa registry shows that Saint Jude RIATA lead extraction and occlusion or critical stenosis of superior venous access are two new independent predictors for cardiac tamponade due to CA/T and VA/T, respectively. Major vascular complications were lower in patients who underwent TLE using mechanical sheaths as compared to powered ones. A strategy of pericardiocentesis followed by a rescue surgical approach seems to be reasonable in order to treat a cardiac tamponade due to CA/T, especially in case of procedure performed in the EP lab.

Supplementary material

Supplementary material is available at *Europace* online.

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