Completely epicardial implantable cardioverter/defibrillator (ICD) and CRT-D systems: A case series and systematic literature review

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Abstract

Background: Epicardial ICD systems and CRT-Ds using high voltage coils represent an alternative to transvenous systems in patients without central venous access and prior device complications including infection.

Objective: We present a case series in the adult population of epicardial ICD/CRTD systems using high voltage epicardial coils. We summarize the existing data regarding techniques, efficacy, and safety.

Methods: A retrospective board approved medical record review was conducted for all patients undergoing epicardial ICD/CRTD placement at our institution between January 2010 and May 2020. The literature was reviewed for prior published trials, case reports, and case series of epicardial high voltage coil insertions.

Results: Eleven patients (six female, mean age 48 years) underwent epicardial ICD/CRTD implant including 5/11 completely epicardial CRTD systems. The procedure was performed via median sternotomy in eight patients, left anterior thoracotomy in two patients, and sub-xiphoid approach in one patient. After a mean follow up of 35 months, appropriate successful shocks were delivered in two (18%) patients and no patients received an inappropriate shock. Three of five (60%) patients had volumetric remodeling with CRT with significant improvement of LV EF. Device-related complications requiring a surgical/percutaneous revision or another DFT test occurred in six patients (54%). One patient died during follow up due to refractory heart failure. No cases of epicardial device infection, coronary artery compression, constrictive pericarditis, or erosion of defibrillator coils into intrathoracic organs were reported. No randomized studies comparing safety and efficacy of traditional transvenous or subcutaneous ICD systems and epicardial ICD systems using contemporary high voltage coils were found nor any studies directly comparing epicardial defibrillator patches versus epicardial coils. Thirteen case series and 24 single case reports published between 2004 and 2020 were identified describing in total a heterogenous group of
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RESULTS CASE SERIES

188 patients with ICD systems incorporating one or more epicardially positioned shock coils.

Conclusion: The use of epicardial defibrillation coils for ICD/CRT-D is a feasible treatment option for patients with either failed or contraindicated transvenous ICD systems. Dedicated epicardial high voltage leads with integrated pace-sense electrodes and specialized delivery tools for minimal invasive implantations may improve longer term outcomes.

KEYWORDS
epicardial defibrillation coils, epicardial defibrillation patches, epicardial ICD, nontraditional ICD, nontransvenous ICD

1 | INTRODUCTION

The growing number of transvenous devices including ICDs and CRTDs has been paralleled by an increase in device related complications. Management of central venous occlusions, device-related infections, and recurrent lead failures are problems frequently encountered by cardiologists in daily practice. Subcutaneous ICDs are a valid option for selected patients avoiding endovascular access entirely but currently do not afford anti-tachycardia pacing, bradycardia protection, or cardiac resynchronization therapy. Epicardial defibrillation systems initially incorporating epicardial patches were abandoned due to the associated perioperative morbidity and high patch failure rates being replaced by transvenous systems. The ability to place epicardial shock leads to perform defibrillation has regained popularity in the past 10–15 years with insertion via sternotomy, mini-thoracotomy, subxiphoid, or video-assisted thoracoscopic approaches. Case reports of fully epicardial cardiac resynchronization defibrillator (CRT-D) systems encompassing epicardial coils exist. The literature regarding the use of completely epicardial ICD/CRT-D including procedural aspects, effectiveness, and safety of high voltage coils in an epicardial position in a contemporary adult patient cohort is not well described. We present a case series of patients undergoing completely epicardial ICD/CRT-D systems at our institution. We also present a systematic review of the current literature of epicardial lead placement to deliver shock therapy.

2 | METHODS

A retrospective institution approved medical record review was conducted for all patients undergoing epicardial ICD/CRT-D placement at our institution between January 2010 and May 2020. Medical records, electrocardiograms, echocardiogram and cardiac MRI reports, implantation reports, device characteristics, in-clinic follow-up device interrogation, and telemetered data and tracings as well as outcome data were analyzed. The literature was reviewed for published studies, case reports, and case series of epicardial ICD/CRTD insertions using contemporary high voltage coils. Electronic searches were performed in English in the Cochrane Library, PubMed, EMBASE, and Medline for articles between January 01, 1980, and October 31, 2020, using medical subject heading (MeSH) terms and relevant text phrases in titles and abstracts. Articles obtained in the literature search were initially screened by relevant title, then abstract, and finally by full article itself. Adult and pediatric case series were included. Key characteristics of the published case reports and series were summarized and compared to our case series.

3 | RESULTS CASE SERIES

3.1 | Patient demographics

Eleven patients were identified (six females, mean age 48 years) who underwent epicardial ICD/CRT-D system implantation incorporating epicardially placed high voltage coils. Baseline characteristics are summarized in Table 1. Underlying cardiac diagnoses included channelopathies (LQTS, exercise-induced VT/VF), congenital heart disease (Ebstein anomaly, congenital pulmonary stenosis, and infundibular RVOT-obstruction, ALCAPA, bicuspid AV), non-ischemic (ARVC, post myocarditis DCM, post radiotherapy DCM), and ischemic cardiomyopathies (CAD, embolic in context of primary APS). Nine patients (82%) had impaired LV function and five had severely impaired function and underwent CRT-D. Two patients (18%) underwent ICD implantation for primary and nine (82%) for secondary prevention. The most common indication for an epicardial system was prior infection of a transvenous device system in five patients (45%). Among those two patients required surgery for removal of giant vegetations and septic emboli, two patients experienced recurrent device infections, and one patient failure of transvenous reimplantation on the contralateral side after extraction of a previous infected device. Other indications included lack of central venous access (n = 1, 9%), large spontaneous thrombus attached to transvenous lead requiring surgical removal (n = 1, 9%), high DFT and failure of multiple non-extractable transvenous systems as well as subcutaneous ICD systems with sensing failure and inappropriate shocks despite repeated repositioning of the subcutaneous coil (n = 1, 9%), insertion at time of concomitant open heart surgery (n = 2, 18%), and prior tricuspid valve repair with concerns for valve integrity in case of transvenous lead insertion (n = 1, 9%). Figure 1 illustrates examples of the indications for an epicardial system in our patient series.
| Pat | G | Age | BMI | Cardiac diagnosis | NYHA | Heart Rhythm | QRS (ms) | Arrhythmias | LVEDV | LV EF | Prior Surgery /Intervention |
|-----|---|-----|-----|-------------------|------|--------------|------|----------|------|------|-----------------------------|
| 1   | F | 53  | 26  | DCM post myocarditis | 2-3  | SR           | 190 ms | m VT      | EDV 183 mL (115 mL/m²) | 20%  | Endo/ epicardial VT Ablation |
| 2   | M | 24  | 22  | Ebstein Anomaly, ASD, right-sided access, pathway | 1   | SR           | 180 ms | VF        | EDV 182 mL (100 mL/m²) | 42%  | Sternotomy TV repair, Cone procedure, Pathway & AFL ablation |
| 3   | F | 40  | 23  | ?LQTS (500 ms) ?arrhythmogenic CMP | 1   | SR           | <100 ms | pVT       | EDV 158 mL (94 mL/m²) | 46%  | no |
| 4   | M | 82  | 29  | Ischemic heart disease | 3   | PsAF         | <100 ms | VF        | EDV 250 mL (125 mL/m²) | 15%  | no |
| 5   | M | 69  | 24  | Arrhythmogenic CMP | 3-4  | PsAF         | No ULR | mVT      | EDV 86 mL (48 mL/m²) | 30%  | AV node ablation |
| 6   | F | 63  | 30  | DCM post Radiotherapy | 2   | SR           | 138 ms | AT        | EDV 129 mL (77 mL/m²) | 26%  | no |
| 7   | M | 38  | 25  | Congenital PS, infundibular RVOTO, VSD | 2   | SR           | 154 ms | VF        | EDV 155 mL (79 mL/m²) | 55%  | Repeated Balloon Valvuloplasty for PS |
| 8   | F | 21  | 26  | ALCAPA with MI, Hypokalemia with 2nd LQT (530 ms) | 2   | SR           | <100 ms | VF        | EDV 192 mL (120 mL/m²) | 39%  | no |
| 9   | F | 52  | 23  | Bicuspid AV | 2-3  | SR           | 160 ms | pVT, VF   | EDV 150 mL (85 mL/m²) | 60%  | tAVR 1994, mAVR 2004 (rupture of tAVR) |
| 10  | M | 38  | 27  | Exercise induced m VT/VF | 1   | SR           | 157 ms | VF        | EDV 146 mL (70 mL/m²) | 46%  | no |
| 11  | F | 57  | 26  | Primary APS with PE, embolic MI 2003, LV thrombus | 2   | SR           | <100 ms | NSVT      | EDV 139 mL (75 mL/m²) | 25-30% | Slow pathway ablation |

Abbreviations: G, Gender; F, Female, M, Male, BMI, Body mass index, DCM, dilated cardiomyopathy, ASD, atrial septum defect, LQTS, Long QT syndrome, (B)AV, (bicuspid) aortic valve, RVOTO, right ventricular outflow tract obstruction, VSD, ventricular septum defect, ALCAPA, anomalous left coronary artery from the pulmonary artery, LAD, left anterior descending coronary, CPVT, catecholaminergic polymorph ventricular tachycardia, APS = Antiphospholipid Syndrome, PE, Pulmonary embolism, MI, Myocardial infarction, NYHA, New York Heart association classification, SR, Sinus rhythm, (Ps)AF, (persistent) Atrial fibrillation, AFL, atrial flutter, AT, atrial tachycardia, (NS)VT, (nonsustained) ventricular tachycardia, mVT, monomorph, pVT, polymorph, VF, ventricular fibrillation, PVC, premature ventricular contraction, AVNRT, AV node re-entry tachycardia, ULR, underlying rhythm, U/RBBB, Left/Right bundle branch block; IVCD = interventricular conduction delay; LV, Left ventricle; RV, right ventricle; EF, ejection fraction, EDV, end-diastolic volume, CABG, Coronary artery bypass graft, BVP, balloon valvuloplasty.
3.2 Procedural characteristics

The procedural and technical specifications of the 11 patients are summarized in Table 2. Insertion was performed via median sternotomy in eight patients (seven with a concomitant indication for cardiac surgery) via left anterior thoracotomy in two patients and a sub-xiphoid approach in one patient. Pulse generators were placed intraabdominally in six patients (55%), left pectoral in three (27%), and right pectoral in two patients (18%). Ten of the patients (91%) received two epicardial separate coils (Transvene SVC 6937A Coil, Medtronic) and in one patient a single coil 6935 Sprint Quattro secure S (Medtronic) transvenous defibrillator lead was used. Coil insertion via sternotomy was associated with variable positioning of ICD coils on the epicardial surface (see Figure 2). Coils inserted via an anterior left thoracotomy were arranged horizontally over the anterior and posterior surfaces of the ventricles. The subxiphoid inserted coil was passively placed over the high posterior LV wall and LA and combined with a left parasternal subcutaneous coil (anatomical position and lead models listed in Table 4). For ventricular sensing and pacing an active fix screw-in bipolar right ventricular epicardial pace-sense leads was placed in 10 patients (91%) with R wave sensing, stimulation thresholds, and pacing impedances within acceptable range at time of insertion in all patients (Supplementary Table 1) with the exception of one patient with arrhythmogenic right ventricular cardiomyopathy. In this patient, an epicardial LV lead was inserted in the RV port due to better R-wave sensing. In one patient, an epicardial DF4 ICD lead was used for pacing and sensing in the atrium in combination with an endovascular RV lead for ventricular pacing and sensing. Mean HV impedance at implant was 42 Ohm (21-70 Ohms). DFT testing was performed at implant in three patients, two patients with two epicardial coils in place were successful at 25J. The DFT test in the third patient with only one epicardial coil failed requiring external rescue and the insertion of an additional subcutaneous coil to achieve adequate safety margin > 10J was necessary. All shocks were programmed to maximal output and biphasic waveforms with initial shock vector in all cases utilizing an anodal shock with active can. The five patients requiring biventricular
| Nr | ICD Indic. | Indication epicardial System | Access | Device config.& pocket location | Aband. Leads | AP/VP% | DFT |
|----|------------|------------------------------|--------|---------------------------------|-------------|--------|-----|
| 1  | 2<sup>nd</sup> | Transven. ICD Infection with large RA vegetation on transvenous leads | Sternotomy | Dual coil CRT-D Abdominal | None | AP 19% | Vp 98% | N.p. |
| 2  | 2<sup>nd</sup> | Prior TVR for Ebstein Anomaly with epicardial PM in situ Failed S-ICD screening | Re-Do Sternotomy | Dual coil ICD Left subpectoral | None | AP 0.1% | Vp 0.5% | Success 1x25J |
| 3  | 2<sup>nd</sup> | Transven. ICD associated endocarditis with large vegetation / septic emboli | Sternotomy (concomitant TVR, ICD removal) | Dual coil ICD Right pectoral | None | AP 62% | Vp 2.5% | N.p. |
| 4  | 2<sup>nd</sup> | Recurrent transven ICD associated endocarditis and electrical storm | Sternotomy (CABG, LV aneurysmectomy) | Dual coil CRT-D Abdominal | None | AP PsAF | BiP 91% | N.p. |
| 5  | 2<sup>nd</sup> | Transven. CRTD infection with failed contralateral LV lead implant after extraction and recurrent bacteriemia | Anterior left thoracotomy | Dual coil CRT-D Abdominal | EpicardLV / RV leads | BiP 99% | Success 1x25J |
| 6  | 1<sup>st</sup> | Failed tv attempt due to SVC obstruction | Anterior left thoracotomy, sternal extension | Dual coil CRT-D Abdominal | None | AP < 1% | BiP 99% | N.p. |
| 7  | 2<sup>nd</sup> | Failed S-ICD screening open cardiac surgery for underlying cardiopathy | Sternotomy (concomitant TPVR, musc. resection) | Dual coil ICD Left pectoral | None | AP 0% | Vp < 1% | N.p. |
| 8  | 2<sup>nd</sup> | Cardiac surgery for ALCAPA repair | Sternotomy | Dual coil ICD Left pectoral | None | AP 0% | Vp 0% | N.p. |
| 9  | 2<sup>nd</sup> | Recurrent ICD associated (left and right-sided) and prosthetic valve endocarditis, leftsided axillary vein obstruction | Re-re sternotomy (concomitant AV surgery) | Dual coil CRTD with 2 RV leads Abdominal | None | AP 2% | Vp 99% | N.p. |
| 10 | 2<sup>nd</sup> | Recurrent shock lead failure/ high DFTs of transvenous ICD leads in RV, SVC and Coronary sinus position and S-ICD with sensing failure and inappropriate shocks | Subxiphoid | Dual coil ICD Abdominal | 4 tv coils | AP 0% | Vp 0% | 3x Failed 1x25J success (add. s.c. Lead) |
| 11 | 1<sup>st</sup> | Large spontaneous thrombus on transvenous ICD leads requiring surgical removal | Sternotomy | Dual coil CRT-D with LV turned off (back up) Right pectoral | SVC coil | AP 48% | Vp 2.3% | N.p. |

* All epicardial ICD coils are Transvene SVC 6937A, Medtronic, with exception of Pat. Nr 10: 6935 Sprint Quattro secure S MDT; all Shock Vector initially set to CoIl to CoIl/Can, all Shock waveforms biphasic. Abbreviations: 2<sup>nd</sup> = secondary prevention; 1<sup>st</sup> = primary prevention; L, left; R, right; tv, transvenous; CS, coronary sinus; S-ICD, subcutaneous ICD; SJM, St Jude Medical (now abbott); MDT, Medtronic, DFT defibrillation fibrillation threshold test (at time of insertion), RA, right atrium, RV, right ventricle, LV, left ventricle, ant., anterior, post., posterior, inf., inferior, vert., vertical, hor., horizontal, VT, ventricular tachycardia, VF, Ventricular fibrillation, SVC, superior vena cava, AP, atrial pacing, VP, ventricular pacing, BiP, biventricular pacing, N.p., not performed, s.c., subcutaneous, P/S leads, pace-sense leads.
FIGURE 2  Epicardial Coil Placement: Positioning depending on access, generator position, tissue suitability, anatomical course of coronary artery branches and number of coils inserted. Examples from our case series include:
a. Posterior-superior LV & inferior RV wall, abdominal generator (generator not shown)
b. Diaphragmatic side of LV & RV with base to apex alignment, right pectoral generator
c. Vertical alignment on anterior & posterior walls of LV, left pectoral generator
d. Horizontal alignment on anterior & posterior surface, abdominal generator (generator not shown)
e. Vertical over anterior RV wall & horizontal over postero-inferior wall, left pectoral generator
f. Vertical over anterior LV wall & horizontal over postero-inferior wall, right pectoral generator (abandoned SVC coil)

pacing received an additional active fix bipolar epicardial LV pace-sense lead to allow cardiac resynchronization therapy. In one patient, the initial LV lead was capped due to lack of capture despite maximum output and replaced by a second LV lead in a different position (the initial lead was not removed as it was already screwed in myocardium).

4  COMPLICATIONS AND FOLLOW UP

4.1  Acute complications

Acute peri-procedural complications occurred in seven patients (64%) (Table 3). Three major complications were primarily associated with the concomitantly performed cardiac surgery and pre-existing comorbidities (major bleeding due to extensive collaterals around an anomalous left coronary artery originating from the pulmonary artery requiring transfusion, acute-on-chronic kidney insufficiency requiring renal replacement therapy post-surgery in a kidney transplant recipient with pre-procedure severe kidney impairment, cardiogenic shock in a patient with severe biventricular impairment with low cardiac output and recurrent VT). One patient required a revision of the epicardial coil due to displacement within 7 days after the initial insertion and one patient developed atrial flutter post-surgery requiring cardioversion.

4.2  Follow up and chronic complications

Mean follow up was 35 months (range 9–122 months). During follow up, four appropriate and successful shocks were delivered in two (18%) patients (three for VT and one for VF). A further four patients had non sustained ventricular tachycardias and seven patients supraventricular tachycardias appropriately detected and discriminated. No patient received inappropriate shock therapy at follow-up. Mean HV impedance rose from 42 to 70 Ohm (26 to > 200 Ohm), and during
### TABLE 3  Complications – periprocedural and follow-up (mean 35 months, range 9-122)

| Peri-procedural (n) | n = 7 (64%) |
|---------------------|------------|
|                     | n = 1 Cardiogenic shock |
|                     | n = 1 AKI with RRT post-surgery (kidney transplant recipient) |
|                     | n = 1 Major bleeding requiring multiple transfusion |
|                     | n = 1 Unsuccessful DFT at time of implant requiring addition of subcutaneous coil |
|                     | n = 1 Epicardial Coil displacement on day 7, repositioning via sub-xiphoid access |
|                     | n = 1 High LV lead threshold at time of implant requiring insertion of 2nd LV lead |
|                     | n = 1 Atrial flutter post-surgery |

| Inappropriate shock | n = 0 (0%) |
|---------------------|------------|
| Unsuccessful shock  | n = 0 (0%) |

| Failed arrhythmia detection | n = 1 (9%) |
|----------------------------|------------|
|                            | - Slow VT below detection zone |

| PMT | n = 2 (18%) |
|-----|-------------|
|     | - Misdiagnosed as atrial tachycardia in 1 patient |

| Lead dysfunction | n = 6 (54%) |
|------------------|-------------|
| (a) requiring intervention: | |
| - n = 2: new pace-sense RV lead (1x poor R wave - re-do sternotomy and lead removed, 1x noise on RV lead with pacing inhibition - sub-xiphoid approach and lead abandoned) |
| - n = 1: switching RV and LV lead on header (noise on RV lead with risk of inappropriate shock - re-opening generator pocket only) |
| - n = 1: new subcutaneous HV coil (fracture of both epicardial coils, epicardial coils abandoned) |
| - n = 2: repeated DFT test (low R wave sensing and after change of Shock vector) |
| (b) surveillance only: | |
| - n = 1: RA lead noise with inappropriate mode switch (sensitivity adjusted) |
| - n = 1: high RA threshold (persistent AF in further FU, no revision) |
| - n = 1: slowly rising RV lead threshold and decrease of R wave sensing |

| Infection | n = 0 |
|-----------|------|

| Hospitalisation | n = 8 (73%)* |
|-----------------|-------------|
|                 | - n = 6 for lead dysfunction / revision / repeat DFT |
|                 | - n = 1 refractory heart failure |
|                 | - n = 2 after appropriate shock |
|                 | - n = 1 for elective atrial flutter ablation |

| Death | n = 1 (9%) |
|-------|------------|
|       | - refractory heart failure, Tachy-Therapy turned off (palliation) |

| Other | n = 0 (0%) |
|-------|------------|
|       | - no Coronary artery compression, Constrictive Pericarditis, Cardiac strangulation, Erosion |

**Abbreviations:** n = number of patients (% within this case series); AKI, acute kidney insufficiency; RRT, renal replacement therapy; AFL, atrial flutter.

*If same patient hospitalized more than once counted as 1.
Follow up, two patients underwent DFT testing due to poor R wave sensing and after a change of shock vector polarity (both successful at 25J). Device related complications requiring a surgical intervention occurred in four patients (36%) at follow up (see Table 3, Figure 3). One patient with fracture of one epicardial coil was initially switched to a different shock vector but suffered a coil fracture on the second epicardial coil requiring complete abandoning of his epicardial system and insertion of two subcutaneous coils. Two patients received new RV pace-sense leads, one due to noise with risk of inappropriate shocks and pacing inhibition in a pacing dependent patient and the second for R wave under-sensing. In one patient with noise on the RV lead, RV and LV leads were switched on the header to avoid inappropriate shocks. One patient using the epicardial DF4 lead for atrial sensing and pacing developed a loss of capture. As this patient later developed persistent atrial fibrillation no revision was performed. One patient had minimal deterioration of their pace-sense lead parameters in follow up not requiring acute revision but intensified surveillance. One patient was found to have episodes of noise on the RA lead leading to inappropriate mode switching but no further events were noted after adjusting atrial sensitivity. In total, eight patients were hospitalized during follow up for above mentioned device-related issues with surgical revision, DFT testing, or after appropriate shock for further workup. One patient was hospitalized due to uncompensated heart failure and one patient electively for atrial flutter ablation. One patient died during follow up due to refractory heart failure (ICD tachy-therapies were turned off in the end-of-life setting). No cases of epicardial device infection, coronary artery compression, constrictive pericarditis, or erosion of defibrillator coils into intrathoracic organs occurred during follow up.

Of the five patients with completely epicardial CRTD system, four received cardiac synchronization therapy, and at follow up, three of four (75%) had volumetric remodeling with significant improvement of their left ventricular EF (defined as > 10% reduction in left ventricular volumes). In the fifth patient, the initially inserted LV lead was programmed off as a backup as ventricular pacing requirement remained low and the QRS narrow during follow up.

5 | SYSTEMATIC LITERATURE REVIEW

No randomized studies comparing safety and efficacy of traditional transvenous or subcutaneous ICD systems and epicardial ICD systems using contemporary high voltage coils were found nor any studies directly comparing epicardial defibrillator patches versus epicardial coils. We identified 13 case series (nine in a pediatric-adolescent population including 4 to 46 patients, four in an adult general cardiology population including 3 to 42 patients) and 24 single case reports (nine children, 15 adults) published between 2004 and 2020 describing in total a heterogenous group of 188 patients (118 pediatric-adolescent patients, 70 adults) with ICD systems incorporating one or more epicardially positioned shock coils. Table 4 and 5 summarize the main findings of the published case series and reports, including indications, surgical approaches and ICD configurations as well as DFT and outcome when reported. Details for each of the included publications have been summarized in Supplement Table 3.

Insertion approaches for epicardial coils included median sternotomy (in 39%) or left lateral (mini-) thoracotomy (27%) as well as
| TABLE 4 Overview literature |
|-----------------------------|
| **Case reports** | Total | Pediatric-Adolescent | Adult |
| Case series | 13 | 9 | 4 |
| Publication Date | 2004-2020 | 2006-2018 | 2004-2020 |
| Nr. of patients | 188 | 118 (63%) | 70 (37%) |

**Baseline Characteristics & Device specifications**

| Age (range) | Total | Pediatric-Adolescent | Adult |
|-------------|-------|---------------------|-------|
| 5w-80y | 188 | 118 (63%) | 70 (37%) |
| 5w-18y | 11 | 6 | 5 |
| 19 – 80y | 11 | 6 | 5 |

**Underlying Cardiopathy**

| Cardiopathy | Total | Pediatric-Adolescent | Adult |
|-------------|-------|---------------------|-------|
| Ischemic heart disease | 24 | 9 | 15 |
| Nonischemic DCM | 13 | 9 | 4 |
| HCM | 13 | 11 | 2 |
| ARVC | 3 | 3 | 0 |
| LQTS | 30 | 30 | 0 |
| Brugada Syndrome | 2 | 2 | 0 |
| CPVT | 2 | 2 | 0 |
| SQTS | 1 | 1 | 0 |
| Idiopathic VF/VT | 2 | 2 | 0 |
| Congenital heart disease | 17 | 16 | 1 |
| **N/R** | 68 (36%) | 22 | 46 |

**Indications for epicardial system**

| Indication | Total | Pediatric-Adolescent | Adult |
|------------|-------|---------------------|-------|
| Lack of Venous access | 27 | 13 | 14 |
| Infection / Endocarditis | 17 | 0 | 17 |
| Concomitant open heart surgery | 6 | 4 | 2 |
| Transven/subcutaneous device failure | 9 | 0 | 9 |
| Tricuspid valve replacement | 1 | 0 | 1 |
| Age/Patient Size | 90 | 90 | 0 |
| **N/R** | 38 (20%) | 11 | 27 |

**Access / surgical approach**

| Approach | Total | Pediatric-Adolescent | Adult |
|----------|-------|---------------------|-------|
| Sternotomy | 73 | 45 | 28 |
| Left Thoracotomy | 51 | 30 | 21 |
| VATS (Robotic) | 7 | 0 | 7 |
| Subxiphoidal incision/puncture | 41 | 33 | 8 |
| **N/R** | 16 (8%) | 10 | 6 |

**Generator pocket**

| Pocket | Total | Pediatric-Adolescent | Adult |
|--------|-------|---------------------|-------|
| Abdominal | 142 | 96 | 46 |
| Left pectoral | 22 | 1 | 21 |
| Right pectoral | 2 | 0 | 2 |
| **N/R** | 22 (12%) | 21 | 1 |

**Number of inserted HV Coils**

| Coils | Total | Pediatric-Adolescent | Adult |
|-------|-------|---------------------|-------|
| 1 Single coil | 74 | 59 | 15 |
| 2 Single coil | 61 | 14 | 47 |
| Dual coil | 28 | 26 | 2 |
| Hybrid** | 7 | 1 | 6 |
| **N/R** | 18 (10%) | 18 | 0 |

**Model of HV Leads**

| Model | Total | Pediatric-Adolescent | Adult |
|-------|-------|---------------------|-------|
| Standard transvenous | 43 | 38 | 5 |
| Medtronic Transvene 6937 SVC | 79 | 33 | 46 |
| Medtronic 6996-SQ | 17 | 3 | 14 |
| Tripolar SQ | 1 | 0 | 1 |
| **N/R** | 48 (25%) | 44 | 4 |

**CRTD System**

| System | Total | Pediatric-Adolescent | Adult |
|--------|-------|---------------------|-------|
| Completely Epicardial | 5 | 0 | 5 |
| Hybrid** | 1 | 0 | 1 |

(Continues)
minimally invasive video-assisted thoracoscopic (5%, reported for adults only) and sub-xiphoid access (22%). The inserted defibrillator coils were either off-label use of standard transvenous single or dual coil high voltage leads or the subcutaneous defibrillator lead 6996-SQ (Medtronic) or in one case a subcutaneous 3-limb Endotak SQ array (Boston Scientific). In the majority of pediatric cases, only one high voltage lead was inserted, whereas in adults, most commonly two separate single coil leads were employed. Positioning of coils on the epicardial surfaces of the right and left ventricles was heterogenous guided by underlying pathology, access, generator placement, and patient size. One exceptional coil configuration was reported by Ozyuksel et al. performing a sternotomy and placing a coil tightly looped around itself in a snail-shell-like appearance on the RVOT. For minimal invasive thoracoscopic or sub-xiphoid approaches, innovative techniques for “halo,” “sling,” or “loop” configurations of single or dual coils are described. The majority of high voltage coils were actively secured by sutures on the epicardium or the inside of the parietal pericardium. Pulse generators were placed in the pectoral area (left and right described) in adults, whereas an abdominal placement (or supra-diaphragmatic) was preferred in the pediatric populations. No failed insertion attempts were reported. DFT testing at time of insertion was performed in 11/13 case series and in 21/24 case reports. Only five out of 180 DFT tests were reported as unsuccessful at time of insertion (three pediatric, two adult cases) and subsequently addressed by a change of shock vector or addition of a subcutaneous or second epicardial coil. One case series included epicardial and subcutaneous coils and described a lower DFT (13 ± 4J) in the epicardial systems as compared to the subcutaneous ICDs (19 ± 7J). Another pediatric case series compared anterior versus posterior coil placement via a sub-xiphoid approach and abdominal generator and interestingly found lower DFTs in the anterior coil configuration though overall DFTs were low in both groups (anterior 5J, posterior 10J). Separate epicardial bipolar pace-sense leads were inserted at the time of high voltage coil placement. No cases were described using the epicardial ICD lead for pacing and sensing. Combination of transvenous and subcutaneous systems (either as part of the shock circuit or for ventricular pacing and sensing) with the epicardial coils were reported. Several single case reports in adult patients described the use of a totally epicardial CRTD system. Perioperative morbidity was dependent on surgical approach, but generally overall complication rates were acceptably low. No perioperative deaths were described.

Follow up ranged between 1 to a maximum of 51 months. Follow-up intensity and modality and outcome assessment and reporting was very heterogenous. Five case reports and nine case series reported cases of appropriate successful shocks during follow up. Successful application of ATP for VT is mentioned in one pediatric case report. Three Pediatric case series described inappropriate shocks due to conductor fracture, insulation break, and failed discrimination of atrial tachycardias. In one case series including predominantly young adults, coil fractures occurred in 21% within 18 months after implantation. None of the single case reports described any long-term complication, unsuccessful, or inappropriate shocks or revision. A case series dedicated to prevalence of epicardial coronary artery compression due to epicardial leads in pediatric and ACHD population found only two out of eight patients with epicardial coils had clinically relevant compression. Three cases or pericarditis within one month after implantation and one case of a late pericardial tamponade at 39 postimplant was described. No cases of constrictive pericarditis or erosion or fistula formation into intrathoracic organs were reported.

### DISCUSSION – THE CONTEMPORARY ROLE OF EPICARDIAL IMPLANTABLE CARDIOVERTER DEFIBRILLATORS

First-generation epicardial ICDs employing patches were initially used for a high-risk secondary prevention population given the need for cardiac surgery for placement of two to three epicardial defibrillator patches originally consisting of a semirigid titanium mesh embedded in a plastic square (CPI, Cardiac Pacemaker Inc.) sutured directly on the heart and large generators requiring intraabdominal placement. Technological progress led to a downsizing of the ICD components enabling transvenous lead insertions and pectoral generator placements. This approach replaced epicardial systems with studies demonstrating lower perioperative morbidity and mortality. Contemporary transvenous defibrillators provide highly efficient tachytherapies due to high output energy biphasic waveform shocks with programmable tilt and duration and the option of including an active
TABLE 5  Overview reported outcome in published case reports/series

| Time of follow-up | Total 1-72mo | Pediatric-Adolescent 1-35mo | Adults 1-72mo |
|-------------------|--------------|-----------------------------|----------------|
| **(A) DEVICE PERFORMANCE** |
| Tachy Therapies | | |
| Appropriate Shocks: (Number of total shocks) | 119 | 110* | 9 |
| Successful ATP | 1 | 1 | 0 |
| HV Lead performance** | | |
| Stable HV impedance | 38 | 25 | 13 |
| Stable DFT | 8 | 1 | 7 |
| High DFT requiring additional coil | 3 | 1 | 2 |
| CRT response** | | |
| Responder | 3 | 0 | 3 |
| Not reported | 3 | 0 | 3 |
| **(B) COMPLICATIONS** |
| Acute perioperative | | |
| Pericardial effusion/ tamponade | 2 | 1 | 1 |
| Acute Pericarditis | 3 | 0 | 3 |
| Pneumothorax | 2 | 2 | 0 |
| Pleural effusion | 1 | 1 | 0 |
| Pulmonary oedema | 1 | 0 | 1 |
| AKI | 1 | 0 | 1 |
| Soft tissue infection | 1 | 1 | 0 |
| Faulty connection to header | 1 | 1 | 0 |
| Acute coil detachment or dysfunction | 2 | 2 | 0 |
| Conversion to open heart surgery | 1 | 0 | 1 |
| In Follow Up | | |
| Epicardial Coil fracture requiring replacement | 10 | 1 | 9 |
| Epicardial Pacing lead fracture or insulation break | 12 | 10 | 2 |
| Electrical storm | 2 | 2 | 0 |
| Inappropriate shocks | 13 | 13 | 0 |
| Unsuccessful shocks | 0 | 0 | 0 |
| Failed ATP | 0 | 0 | 0 |
| Death | 1 | 1* | 0 |
| Constrictive pericarditis | 0 | 0 | 0 |
| Pericardial adhesion or epicardial fat impairing lead performance | 2 | 1 | 1 |
| Coronary artery compression | 2 | 2 | 0 |
| Cardiac Strangulation | 0 | 0 | 0 |
| Lead erosion / Fistula formation | 0 | 0 | 0 |
| Device infection | 0 | 0 | 0 |

*total number of shocks incl. recurrent shocks in same patient (mainly driven by two pediatric case series with 58 shocks in seven patients and 38 shocks in four patients).
**cumulative Patient numbers of all publications, in which respective information was provided.
*both 2*rd to LQTS.
*secondary to seizure.
can in the shock circuit and the ability to deliver CRT with biventricular pacing. The enhanced detection and discrimination algorithms and possibility of anti-tachycardia-pacing has reduced the incidence of inappropriate and appropriate shocks and thereby increased patient acceptance and battery life.

6.1 Alternative options for shock lead placement

The transvenous approach is not universally applicable and various patient characteristics or complications may render it impossible. These include patients with lack of central venous access or recurrent infections from endocardial systems. The introduction of the subcutaneous ICD has revolutionized practice in patients in whom a transvenous approach is not possible or desirable however not all patients are suitable due to sensing issues. Also, in patients requiring pacing and or resynchronization the subcutaneous ICD does not afford this and anti-tachycardia pacing is not possible. Over the last few years, several case reports have shown that the combination of a S-ICD and a leadless pacemaker is feasible, more recently also combinations with the WISE CRT (wireless stimulation endocardially) have been described, but complex interaction between the various systems need to be considered.

In patients with lack of central venous access via the upper thoracic veins unsuitable for interventional revascularization with venoplasty/stenting or vascular surgery alternative insertion routes have been described via a transfemoral/iliac or transhepatic access. A more recently reported solution for cardiac device implantation in the presence of complex thoracic vein occlusion is the “inside-out” central venous access. The transthoracic transatrial access with placement of defibrillator coil into the RV via an atriotomy requiring a thoracotomy has been successfully reported even in small children.

For selected patients with high DFT with standard transvenous ICD systems or tricuspid valve abnormalities (including mechanical valve prosthesis), case reports/series demonstrated that insertion of an ancillary defibrillator coil in the coronary sinus, V. hemiazygos (with right sided generator), or left subclavian veins as part of a dual coil system is feasible.

6.2 Epicardial systems

Epicardial and pericardial systems may represent a valuable and important option in selected patients requiring defibrillation and pacing therapy. The most common indications for epicardial ICDs are summarized in Supplement Table 2 and include lack of venous access, recurrent infectious complications, tricuspid valve related pathologies, as well as poor transvenous lead performance in patients not suitable for S-ICD systems, particularly if requirements for pacing or cardiac resynchronization therapy are present.

Lead placement within the pericardial space can be achieved with differing access options each having its distinct benefits and site and access specific complications and short comings. Epicardial lead placements are more common though some have advocated a pericardial position in order to minimize the risk of constrictive pericarditis, interference of heart movement, and coronary artery damage. Traditionally, insertion has been performed via sternotomy or left-sided thoracotomy with the benefit of near unrestricted access to the surface of the heart allowing for optimal electrical mapping for pace/sense leads and coil positioning as well as active lead fixation. Nowadays, open heart surgery is mostly reserved for patients requiring concomitant cardiac surgery whereas minimal invasive approaches via video-assisted thoracoscopy or sub-xiphoid access are preferred for epicardial ICD insertion to reduce perioperative morbidity. However, dedicated delivery tools for these approaches are lacking. Regardless of the access, placement of the epicardial coils and generator should aim to encompass as much of the ventricular myocardium in between them as possible. Insufficient separation of anode and cathode of the high voltage circuit may result in reduced defibrillation efficacy. DFT testing at the time of insertion is highly recommended for all epicardial ICDs to assure appropriate function.

Separate epicardial pace-sense leads for arrhythmia detection are required and may be used for delivery of brady- and/or cardiac resynchronization therapy. The possibility of using a left ventricular lead position for R-wave sensing is particularly valuable in patients with right heart cardiopathies including ARVC. Also, the comparatively minor anatomical constraints on the epicardial surface allow for optimal positioning of the LV electrode for biventricular pacing in the area of maximal electrical delay. Some authors support the routine insertion of back up leads in case of lead failure, though this needs to be balanced against the risk of introducing additional hardware into the pericardial space and thereby increasing the risk of complications.

Patch-based epicardial ICD systems have been traditionally associated with higher complications rates peri-procedurally and poor long term lead performance with epicardial defibrillator patch failure reported in 28% within 4 years. Most commonly fractures, dislodgments and crinkling were documented within the first 8 ± 5 months. Epicardial patches are no longer used and the practice of using “off label” transvenous or subcutaneous ICD leads within the pericardium has developed. These may share some inherent limitations, including access-specific periprocedural risks, lead-related complications such as displacement, perforation, infection, or intrinsic lead failure (e.g., conductor fracture, insulation break). Coronary artery compression is a potential concern with epicardial lead placement with pediatric case series showing an incidence of 5.5%, although adults might be at a lower risk due to larger retrosternal space and more epicardial fat. Another important potentially lethal risk in the growing or enlarging heart is cardiac strangulation (incidence 2.3%) due to a mismatch between lead length and the heart size with subsequent cardiac ischemia, heart failure, and sudden circulatory collapse requiring immediate removal. Epicardial patch insertion was associated with post-pericardiotomy syndrome and constrictive pericarditis in one case series requiring re-operation in 8% within 10–18 months after insertion. For epicardial defibrillation coils, no cases of constrictive pericarditis have been reported although this might be due to a failure to recognize this. A potential proarrhythmic effect from epicardial
electrodes has been hypothesized if leads are placed in proximity to diseased myocardium possibly due to an increased dispersion of repolarization in the vicinity of the scar. A very rare but serious potential complication is migration and erosion of the lead into intrathoracic organs with fistula formation or mediastinitis. Several case reports describe broncho-pericardial fistulas caused by erosion of an epicardial patch into adjacent lung parenchyma in the setting of chronic device infection and should be suspected in patients with hemoptysis and air between patch and heart on X-ray and CT. No cases of erosion of epicardial coils have been reported.

Long-term outcome and safety data of epidurally placed ICD coils are not well described; therefore, close clinical monitoring and regular device checks are highly recommended at a center with expertise. Any new and/or unexplained cardiac symptom or signs or suspicious extracardiac symptom (e.g., hemoptysis, gastrointestinal bleeding) should prompt further diagnostic workup at a very low threshold particularly if concerns for coronary artery compression, cardiac stran-
gulation, constrictive pericarditis, or device erosion and fistula formation exist. It should be noted that for permanent epicardial systems there is limited data regarding the safety of MRI scanning. In vitro studies observed a significant heating effect in abandoned epicardial leads (up to seven times higher than the same setup with a connected device) and even for epicardial leads connected to a device the heating was in the tested configuration similar to the heating of an abandoned transvenous lead (an MRI nonconditional situation). Transvenous MR conditional electrodes in epicardial position connected to a MR conditional generator may in theory have a lower risk but temperature rise cannot be predicted. None of the common device manufactures offer MR conditional epicardial leads.

Randomized data regarding the use of completely epicardial CRT-D systems is lacking and restricted to case reports. To our knowledge, our series represents the largest series to date of completely epicardial CRT-Ds. Although this is a feasible approach and reported outcome for surgically placed epicardial left ventricular leads are encouraging longer term data in terms of CRT response and remodeling for completely epicardial systems is sparse. As with traditional CRTs, a biventricular pacing percentage close to 100% is essential for optimal response and appropriate biventricular capture should be confirmed with 12-lead ECG. A representative ECG for epicardial CRT is displayed in Figure 4.

1628 | CONCLUSION

Our case series demonstrate that epicardial implantable cardioverter-defibrillator systems with coils instead of patches appear to be a feasible option even for the most complex of cardiac patients who are otherwise unsuitable for standard transvenous or subcutaneous systems and it is practicable to incorporate this into fully epicardial systems with cardiac resynchronization. However, in the longer term, there are
significant drawbacks and a high rate of need for interventions related to lead related issues. Data regarding safety and efficacy is sparse and limited to case series, single case reports and basic research studies. Dedicated epicardial defibrillator coils with integrated paced-sense capabilities and specialized delivery tools for minimal invasive insertion approaches would be desirable to reduce hardware, shorten procedure times, and improve lead performance and survival.

DATA AVAILABILITY STATEMENT
The data is available from the corresponding author on reasonable request only due to privacy restrictions.

FUNDING
The authors did not receive any financial support for this manuscript.

AUTHOR CONTRIBUTION
JBT collected the data, reviewed the literature, and wrote the manuscript. CAR, CB, and ER critically reviewed and approved the final manuscript version for submission.

ETHICS APPROVAL
Medical Board Approval gained.

PATIENT CONSENT
Informed consent gained.

CONFLICT OF INTEREST
No conflicts of interest to declare.

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SUPPORTING INFORMATION
Additional supporting information may be found online in the Supporting Information section at the end of the article.

How to cite this article: Tonko JB, Blauth C, Rosenthal E, Rinaldi CA Completely Epicardial Implantable Cardioverter/Defibrillator (ICD) and CRT-D systems: A case series and systematic literature review. Pacing Clin Electrophysiol. 2021;44:1616–1630. https://doi.org/10.1111/pace.14318