Non-traditional implantable cardioverter-defibrillator configurations and insertion techniques: a review of contemporary options

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Abstract

Implantable cardioverter-defibrillators (ICDs) have revolutionized the treatment of acquired or inherited cardiac diseases associated with a high risk of sudden cardiac death due to ventricular tachyarrhythmias. Contemporary ICD devices offer reliable arrhythmia detection and discrimination algorithms and deliver highly efficient tachytherapies. Percutaneously inserted transvenous defibrillator coils with pectoral generator placement are the first-line approach in the majority of adults due to their extensively documented clinical benefit and efficiency with comparably low periprocedural implantation risks as well as the option of providing pain-free tachycardia treatment via anti-tachycardia pacing (ATP), concomitant bradycardia protection, and incorporation in a cardiac resynchronization therapy if indicated. Yet, expanding ICD indications particularly among younger and more complex patient groups as well as the increasingly evident long-term consequences and complications associated with intravascular lead placements promoted the development of alternative ICD configurations. Most established in daily clinical practice is the subcutaneous ICD but other innovative extravascular approaches like epicardial, pericardial, extra-pleural, and most recently substernal defibrillator coil placements have been introduced as well to overcome shortcomings associated with traditional devices and allow for individualized treatment strategies tailored to the patients characteristics and needs. The review aims to provide practical solutions for common complications encountered with transvenous ICD systems including restricted venous access, high defibrillation/fibrillation thresholds (DFTs), and recurrent device infections. We summarize the contemporary options for non-traditional extravascular ICD configurations outlining indications, advantages, and disadvantages.
Keywords
Non-traditional implantable cardioverter-defibrillator • Epicardial implantable cardioverter-defibrillator • Subcutaneous implantable cardioverter-defibrillator • Extra-pleural implantable cardioverter-defibrillator • Substernal implantable cardioverter-defibrillator • Hybrid implantable cardioverter-defibrillator configurations • High defibrillation/fibrillation threshold • Venous access crisis

Introduction
Implantable cardioverter-defibrillators (ICDs) have revolutionized the treatment of acquired or inherited cardiac diseases associated with a high risk of sudden cardiac death due to ventricular tachyarrhythmias. Contemporary ICD devices offer reliable arrhythmia detection and discrimination algorithms and deliver highly efficient tachytherapies. Percutaneously inserted transvenous defibrillator coils with pectoral generator placement are the first-line approach in the majority of adult patients due to their extensively documented clinical benefit and efficiency with comparably low periprocedural implantation risks as well as the option of providing pain-free tachycardia treatment via anti-tachycardia pacing (ATP), concomitant bradycardia-protection, and incorporation in a cardiac resynchronization therapy if indicated. Yet, expanding ICD indications particularly among younger and more complex patient groups as well as the increasingly evident long-term consequences and complications associated with intravascular lead placements promoted the development of alternative ICD configurations. Most established in daily clinical practice is the subcutaneous ICD but other innovative extravascular approaches like epicardial, pericardial, extra-pleural, and most recently substernal defibrillator coil placements have been introduced as well as to overcome shortcomings associated with traditional devices and allow for individualized treatment strategies tailored to the patients characteristics and needs.

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The need for alternatives

Due to various patient characteristics or complications (summarized in Table 1), traditional transvenous systems may be an unsuitable or contraindicated option. One of the most common causes preventing transvenous device insertions is an occluded or restricted thoracic venous access frequently observed in patients with cardiac devices in situ requiring a revision or upgrade, patients on dialysis, with prior thoracic radiotherapy or congenital heart disease with lack of venous continuity. Furthermore, endovascular leads are naturally exposed to a variety of biological and mechanical stress factors straining their electrical integrity and long-term considerations need to be taken into account particularly in the young. Even though significant technological advances in terms of intravascular hardware biocompatibility and durability have been made, HV lead survival rates remain comparatively low ranging from 91% to 99% at 2 years, 85% to 95% at 5 years, and 60% to 72% at 8 years in studies including leads subject to safety communications or recalls. Likewise, device-related infectious events remain an important complication despite the use of preemptive antibiotics and recent demonstration of further risk reduction by the use of absorbable antibacterial envelopes. They account for 52.8% of indications for extraction. Intracardiac shunts with risk of paradox embolism, recurrent lead displacements, high DFTs, or severe iatrogenic tricuspid valve regurgitation due to lead adherence, entanglement, leaflet perforation, or impingement with associated right heart failure represent further indications for non-traditional configurations.

Various techniques have been developed to overcome limited vascular access and alternative intravascular defibrillator coil positions have been suggested to treat patients with high DFTs or tricuspid valve abnormalities (summarized in Table 2). If intravascular hardware should be avoided, several options for entirely extravascular ICDs are available. Experience and evidence for long-term safety and efficacy data for these novel configurations vary significantly and must be taken into consideration.

Venous access options

For patients with occluded upper central venous access interventional venous revascularization with venoplasty ± stenting or vascular surgery can be an option. If a device is already in situ and requires a revision or upgrade the use of laser or mechanical recanalization tools (with or without lead extraction) can be considered. In case of an unilateral venous occlusion contralateral access and subcutaneous tunnelling of the new lead to the existing generator site may be attempted.

If the patient is deemed unsuitable or declines any of the above-mentioned solutions alternative insertion techniques have been described via a transfemoral/iliac or trans-hepatic access with placement of the defibrillator coils into the RV cavity and tunnelling of the lead body to an abdominal generator. If a pectoral generator placement is preferred despite the presence of complex thoracic vein occlusion the ‘inside-out’ central venous access offers an elegant percutaneous alternative. The latter involves the use of a special needle guide inserted via the femoral vein which is used to puncture through the occluded central vein segment from within the vasculature and advancing a wire to a predefined infra- or supraclavicular exit point (see Figure 1). A further albeit more invasive option is the transatrial access with placement of defibrillator into the right ven- tricular cavity via a thoracotomy and atriotomy. This approach has been successfully reported even in very small patients with otherwise insufficient vessel size or lack of venous continuity and/or the concomitant need for bradytherapy rendering a subcutaneous system unsuitable.

Alternative intravascular defibrillator coil positions

The two main indications for non-traditional intravascular defibrilla- tor coil placements include high defibrillation-fibrillation thresholds and tricuspid valve abnormalities.

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Table 1 Complications of transvenous devices

- Infection/CIED-associated endocarditis (0.6–3.4%/years)
- Venous occlusion/obstruction (up to 37%) ± SVC syndrome
- Lead dysfunction/failure (specific leads up to 3.75%/years)
- Lead displacement (3.1%/16 months)
- Lead perforation 0.14–0.3% ± pericardial tamponade
- Lead-related tricuspid regurgitation associated with right heart failure and increased mortality
- High DFT/failed DFT (2.2%)
- Three-fold risk of systemic embolism in presence of intracardiac shunt
- Risks of extraction (major complication in 0.2–1.8%)
- Overall ICD complication rate in RCTs 9.1%/16 months

CIED, Cardiac implantable electronic devices; DFT, defibrillation/fibrillation threshold; ICD, implantable cardioverter-defibrillator; RCT, randomized controlled trial; SVC, Superior vena cava.
Table 2 Overview alternative venous access options and intravascular coil positions

| Alternative venous access options\(^a\) | Transhepatic | Transfemoral/iliacal | Inside out venous access | Transthoracic transatrial | Coronary sinus (CS) | Hemi-azygos vein | Left subclavian vein |
|----------------------------------------|--------------|----------------------|--------------------------|--------------------------|--------------------|------------------|---------------------|
| Advantage | Permanently minimal invasive | Independent of upper thoracic vein patency | Allows for standard transvenous lead position in right ventricle providing tachytherapy and bradytherapy | Independent of venous patency and vessel size | Standard RV lead position, providing tachytherapy and bradytherapy | Percutaneous insertion | \* Requires sufficiently large vascular calibre of ventricular coronary sinus branch |
| Disadvantage | Exposure to external trauma of long segment of tunnelled lead with risk of fracture/insulation breach | Unfavourable shock vector with abdominal can | Higher lead displacement rates (up to 20% in old series for transfemoral insertion\(^{14}\)) | Thoracotomy required, general anaesthesia | Limited literature on durability, safety/efficacy | Independent of tricuspid valve abnormalities (stenosis, replacement/repair) | Delivery of CRT via CS coil unreliable |
| | | | | | | Shown to be effective in reduction of high DFT | May prevent placement of pace-sense lead into CS or result in interference and may require an epicardial/pericardial of left intraventricular pace/sense lead if RV cavity cannot be accessed |
| | | | | | | Bulk of lead body protected by rib cage | Difficult access for azygos/hemi-azygos vein |
| | | | | | | | Requires separate pace-sense lead (transvenous to RV or CS or epicardial/pericardial) |
| | | | | | | | Higher risk of lead displacement |
| | | | | | | | May require vascular plug to anchor lead |
| | | | | | | | Animal studies revealed problems of lead dislodgement, loss of capture and perforation. |
| | | | | | | | Manufacturer (InnerPulse) dissolved, no long-term human trials. |

CIED, cardiac implantable electronic devices; DFT, defibrillation/fibrillation threshold; ICD, implantable cardioverter-defibrillator; RV, right ventricular; SVC, Superior vena cava; CS coronary sinus.
\(^a\)In occluded thoracic veins unsuitable for interventional or surgical revascularization.
\(^b\)In the setting of high DFTs with traditional ICDs and failure of non-invasive measures or in the presence of tricuspid valve abnormalities precluding standard RV coil placement.
For transvenous ICDs, the praxis of routinely adding a second coil (traditionally in the superior vena cava) has been largely abandoned as similar efficacy was demonstrated for single-coil systems with active can. The decrease in impedance and small reduction in DFT with dual-coil systems in an era of high-output ICDs with biphasic shocks was thought to be offset by an increase in long-term complications. However, for selected patients with high defibrillation fibrillation thresholds (defined as safety margin of <10 V between threshold and maximum output shock in any of the available shock vectors) with standard transvenous ICD systems (RV/SVC coils) case reports/series demonstrated that insertion of an ancillary defibrillator coil in the coronary sinus, hemi-azygos vein, or left subclavian veins is safe, feasible, and successful in lowering the mean DFT. The challenge is the manoeuvring across many angles and delivering large defibrillator coils to these positions (with the exception of the subclavian vein). Also, lead displacement and migration are a concern. Use of a vascular plug to anchor the coil in adequate position to prevent displacement has been described.

Coronary sinus defibrillator coils may also be offered to patients with tricuspid valve abnormalities (including mechanical valve prosthesis precluding access to the RV cavity) provided a sufficiently large ventricular branch is present to accommodate the coil. One possible disadvantage of this position relates to providing transvenous cardiac resynchronization therapy as a small case series found delivery of left ventricular (LV) pacing via the CS unreliable and the coil itself may impede placement of or cause interference with a standard pace-sense LV lead. This is an important concern if both the ventricular pace/sense and HV lead need to be inserted into the coronary sinus. Alternatives for the pace/sense lead insertion in this situation would be an epicardial/pericardial or left intraventricular position.

Sub-septal access and placement of leads into the LV cavity has been described for pacing leads only, but not for high-voltage leads due to difficulties of easing the comparatively bulky defibrillation coil through the septum into the LV cavity and the associated risks of systemic embolism.

**Extravascular implantable cardioverter-defibrillator configurations**

If endovascular lead placements fail or are contraindicated alternative options consist of subcutaneous, epicardial, pericardial, extra-pleural or substernal defibrillator placements, or hybrid configuration combining intra- and extravascular components. With the exception of the subcutaneous ICD no dedicated hardware is available for non-traditional coil positions. Inserted leads are usually off-label transvenous or subcutaneous coils in combination with a standard transvenous ICD generator.

Table 3 gives an overview of the available extravascular ICD configurations.

**Subcutaneous implantable cardioverter-defibrillator**

Over two decades ago, the use of subcutaneous coils and patches in a parasternal or left dorsolateral position as an adjunct to a transvenous or epicardial system to lower high DFTs has been described and remains until today a bailout strategy for this indication including in an adult population. The original subcutaneous array consisted of three ‘fingers’ (coils) requiring extensive dissection with creation of three subcutaneous tunnels for placement. Later case reports demonstrated that single defibrillation coils were as efficacious and that in children subcutaneous array leads with an active can could safely achieve defibrillation even in the absence of a transvenous device.
| Configuration | Advantages | Disadvantages | Pace/sense lead | Evidence |
|---------------|------------|---------------|-----------------|----------|
| Subcutaneous | • Entirely extravascular<br>• Lower risk of systemic infection<br>• Ease and predictability of implant<br>• No risk of embolic events<br>• Lower risks of extraction if required<br>• MRI conditional | • No bradycardia protection or cardiac resynchronization<br>• No anti-tachycardia pacing<br>• Higher shock energy requirement<br>• Large pulse generator size<br>• High % of failed S-ICD screening<br>• Limited diagnostic features<br>• Exposed to external trauma and risk of lead migration/erosion | Not required | Prospective randomized trials and large registry data |
| (2) Subcutaneous single-coil or array without sensing electrodes | • Individualized positioning<br>• Suitable also in small children<br>• Bailout option in high DFT for endovascular systems | • Unsuitable in severe obesity<br>• Separate pace-sense lead required<br>• If used in isolation higher DFT as transvenous/epicardial systems | Epi-or pericardial<br>Transvenous (RV and/or LV) | Prospective randomized trials |
| Epicardial/pericardial | • Independent of vascular continuity/venous patency<br>• No thromboembolic risk<br>• Lower risk for infection<br>• Minimal invasive insertion techniques (sub-xiphoid, VATS) available | • Higher periprocedural morbidity if sternotomy/thoracotomy approach<br>• Specific risks associated with epicardial position (see Table 4)<br>• Higher rates of lead failure<br>• Limited long-term experience with defibrillation coils<br>• Separate pace-sense lead required<br>• Not MRI conditional | Epi- or pericardial<br>Transvenous (RV and/or LV) | Coils: case series/case reports<br>Patches: prospective comparative studies |
| Epicardial/pericardial (1) Off label use of transvenous/subcutaneous coils<br>(2) Patches (historical) | | | | |
| Substernal | • Extravascular<br>• Lead body protected by sternum<br>• Minimal invasive subxiphoid approach<br>• Lower shock energy requirement than subcutaneous ICDs | • No long-term data<br>• Not commercially available | Not required | Feasibility studies/case reports<br>Prospective open-label multicentre trial ongoing |
| Substernal Coil in substernal space in anterior mediastinum | | | | |
The first dedicated entirely subcutaneous ICD for adults (Cameron Health acquired by Boston Scientific in 2012) with a parasternal subcutaneous lead with an 8 cm shocking coil and a distal and proximal sensing electrode and intramuscular generator between the left latissimus dorsi and serratus anterior was introduced in Europe in 2009 and approved by the US FDA in 2012. Large registry and randomized trial data have since confirmed its safety and efficacy and established it as an alternative to the transvenous system in patients without pacing requirement and no cardiac resynchronization therapy (CRT) indication. The latter limitations are currently being challenged as case reports have shown that the combination of S-ICD™ and leadless pacemaker or WISE-CRT (EBR Systems, Sunnyvale, CA, USA) is feasible (see Hybrid ICD systems below). Also, the initial concerns of high inappropriate shock rates in S-ICDs were recently dispersed as studies with 2nd or 3rd generation devices with improved discrimination algorithms and standardized programming algorithms report significantly lower rates (3.1% at 1 year) comparable to many transvenous systems. At present, DFT testing at time of insertion is still recommended but a risk stratification score to predict defibrillation success is currently being evaluated (PRAETORIAN DFT trial) and may identify patients in whom routine DFT testing can be safely omitted.

Ongoing limitations for subcutaneous systems are the high number of unsuitable patients due to sensing issues with failed screening rates reported between 7–8% for 1 vector and 15% for 2 vectors or due to their body habitus in case of significant obesity. Also, the larger generator sizes required for the high energy shocks of up to 80 J may cause patient discomfort, bulging, and aesthetic concerns. Likewise, the extra-thoracic lead position exposes it to environmental mechanical stress with risk of compromising lead integrity as well as lead migration. The latter complication has been significantly reduced by the introduction of a suture sleeve at the xiphoid incision to secure the lead.

### Table 3 Continued

| Configuration          | Advantages                                                                 | Disadvantages                                                                                           | Pace/sense lead* | Evidenceb |
|------------------------|-----------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------|------------------|-----------|
| Extra-pleural           | • Offer bradytherapy and antitachycardia pacing                             | • Experience limited to paediatric/adolescent population                                                | • epi- or pericardial transvenous (RV and/or LV) | Paediatric case series |
|                        | • Extravascular                                                            | • Surgical procedure, left lateral thoracotomy or at time of sternotomy                                 |                  |           |
|                        | • Less lead stress, safe position protected by rib cage in active patients  | • Lead displacement/migration, erosion into thoracic organs                                              |                  |           |
|                        | • Good shock vector in combination with abdominal generators               | • No pace/sense, no ATP, no CRT—requires separate pace-sense leads                                      |                  |           |
|                        | • Suitable for small body size/children                                    | • not MRI conditional                                                                                    |                  |           |
|                        |                                                                           | • Lead displacement/migration, erosion into thoracic organs                                              |                  |           |
|                        |                                                                           | • No pace/sense, no ATP, no CRT—requires separate pace-sense leads                                      |                  |           |
|                        |                                                                           | • not MRI conditional                                                                                    |                  |           |
| Hybrid                 | • Wide range of combinations                                               | • Interactions/interference between systems                                                             | • Epi- or pericardial transvenous (including leadless)         | Feasibility studies/case reports |
|                        | • Individualized to patients characteristics and needs                      | • Combined risk/disadvantages                                                                          |                  |           |
|                        |                                                                           | • Limited experience                                                                                   |                  |           |
|                        |                                                                           | • Usually not MRI conditional                                                                          |                  |           |
|                        |                                                                           | • Non-traditional                                     |                  |           |

ATP, anti-tachycardia pacing; CRT, cardiac resynchronization therapy; DFT, defibrillation/fibrillation threshold; ICD, implantable cardioverter-defibrillator; LV, left ventricular; MRI, magnetic resonance imaging; RV, right ventricular; VATS, Video assisted thoracoscopic surgery

*Traditional transvenous (active fixation) or dedicated epicardial (active or passive fixation) pace/sense leads tunnelled and connected to ICD generator (or CRTD generator if applicable).

bMain text for respective references.
Epicardial/pericardial implantable cardioverter-defibrillator

Due to their complete extravascular position and independency of venous patency epicardial ICD systems are usually considered in the context of lack of vascular access, recurrent endocarditis, or device associated infectious complications, tricuspid valve-related pathologies, and poor transvenous lead performance in patients not suitable for an S-ICD. Epicardial placements are more common though some authors advocate a pericardial position in order to minimize the risk of constrictive pericarditis, interference of heart movement and coronary artery damage.

### Table 4 Complications of epicardial ICD devices

| Complication                                                                 |
|------------------------------------------------------------------------------|
| Coronary artery compression (5.5% in children/CHD)                            |
| Constrictive pericarditis/pericardial adhesions                               |
| Erosion in intrathoracic organs with broncho-/oesophageal-pericardial fistulas |
| Cardiac strangulation (mismatch between lead length and heart size, 2.3% in paediatric patients) |
| Proarrhythmogenic if pacing in proximity to scar                              |
| Elevated DFT with external defibrillation (demonstrated for patches only, not for coils) |
| Impaired lead performance on fibrosed-scarred epi/pericardium or extensive epicardial fat pads |
| Removal of epicardial hardware requires cardiac surgery                       |

CHD, Congenital Heart disease; DFT, defibrillation/fibrillation threshold.

**Figure 2** Examples for hybrid ICD configurations. (A) Transvenous dual-coil ICD including coronary sinus coil and pace-sense leads (yellow arrows, two abandoned, one tunnelled to abdominal generator) with epicardial defibrillator coil (blue arrow). (B) Epicardial ICD with two dual-coil HV leads (blue arrows) and traditional subcutaneous coil (orange arrow) in posterolateral position tunnelled to left pectoral generator. (C) Subcutaneous ICD™ (orange arrow and ⋄) with leadless pacemaker in RV (yellow arrow, Micra) and WISE CRT (red ⋆). (D) Transvenous dual-coil ICD (yellow arrows) with WISE CRT (red ⋆). CRT, cardiac resynchronization therapy; ICD, implantable cardioverter-defibrillator; RV, right ventricular.
Traditionally epicardial systems have been inserted via sternotomy or left-sided thoracotomy with the benefit of unrestricted access to the heart's surface allowing for optimal electrical mapping and active lead fixation. To reduce perioperative morbidity, new techniques using video-assisted thoracoscopy or sub-xiphoid access have been successfully applied and offer a minimal invasive alternative for epicardial systems. Dedicated delivery tools are lacking. For thoracoscopic epicardial lead insertion, special steerable delivery tools are available only for pacing leads but not for defibrillator coils. Delivery systems for sub-xiphoidal introduction of high-voltage leads via a steerable sheath are still investigational.

For epicardial pacing leads, acceptable long-term lead performances have been described; however, the opposite was found for epicardial defibrillation patches, which have been largely abandoned due to high patch failure rates (up to 28% within 4 years). Instead, the off-label deployment of contemporary transvenous and subcutaneous coils passively inserted in the pericardial space or actively sutured on the epicardial or pericardial surface has gained popularity. Theoretically, transvenous defibrillator leads afford ventricular pacing and R-wave sensing; however, in an epicardial position this has been found to be unreliable. Additional epicardial pace-sense leads are required to assure appropriate arrhythmia detection and may also deliver cardiac resynchronization therapy if indicated.

Multiple case series and reports have documented acceptable efficacy and safety of epicardial ICDs employing standard transvenous or subcutaneous coils. Minimal invasive insertion techniques with lower peri-operative morbidity have further contributed to increased use. However, they have not been investigated in randomized prospective trials and recurrent concerns regarding long-term lead performance of the defibrillator coils as well as several rare but severe complications associated with the epicardial position remain (outlined in Table 4). Dedicated follow-up in a specialized centre familiar with these systems is advised and may involve routine radiographic and echocardiographic surveillance as well as continuous monitoring via home monitoring for early identification of complications.

Generally, epicardial ICDs are considered not MRI conditional with only very limited data of small case series regarding the safety of MRI scanning. For epicardial pacing leads, acceptable long-term lead performances have been described; however, the opposite was found for epicardial defibrillation patches, which have been largely abandoned due to high patch failure rates (up to 28% within 4 years). Instead, the off-label deployment of contemporary transvenous and subcutaneous coils passively inserted in the pericardial space or actively sutured on the epicardial or pericardial surface has gained popularity. Theoretically, transvenous defibrillator leads afford ventricular pacing and R-wave sensing; however, in an epicardial position this has been found to be unreliable. Additional epicardial pace-sense leads are required to assure appropriate arrhythmia detection and may also deliver cardiac resynchronization therapy if indicated.

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**Extra-pleural implantable cardioverter-defibrillator**

Paediatric and adolescent population case series described successful placement of an extra-pleural defibrillator coil between the parietal pleura and thoracic wall along the 3rd intercostal space inserted via left lateral thoracotomy or sternotomy. Inserted defibrillator coils were off-label standard transvenous or subcutaneous leads and combined with epicardial pace-sense leads. Generators were placed abdominally or in a sub-cardiac pocket.

Outcome data showed reasonable efficacy and safety in follow-up of up to 5 years. The extra-pleural position prevents complication associated with intravascular leads, protects the lead body from external trauma and tension within the thoracic cage and allows for a favourable shocking vector in combination with an abdominal generator. Disadvantages include the invasive nature of the insertion including the risk of damage to the lung, the need for separate (epicardial or transvenous) pace-sense leads and relatively frequent surgical revisions including for lead failure.

**Substernal implantable cardioverter-defibrillator**

To overcome the limitations of subcutaneous and epicardial ICDs in adult patients but maintaining the benefits of an extravascular position, placement of a defibrillator lead in the substernal space has been proposed. The defibrillation coil can be inserted minimal invasively via a sub-xiphoid approach with a tunnelling tool kept close to the posterior surface of the sternum and is combined with a generator in the left midaxillary line. Initial case reports described the use of transvenous SVC coils in conjunction with epicardial pacing leads or the use of standard subcutaneous coils with integrated sensing electrodes. Recently, a dedicated substernal defibrillator system has been developed and feasibility studies demonstrated successful defibrillation in adult patients with shock energies comparable to transvenous devices and substantially lower than subcutaneous ICDs allowing for smaller generator sizes. First-In-Human pilot studies yielded encouraging results and also proved feasibility of appropriate R-wave sensing and pacing capture from the substernal space allowing for complementary anti-tachycardia pacing and bradycardia protection.

The extravascular substernal defibrillator is an investigational device and not commercially available. A prospective open-label multicentre trial to further evaluate safety and efficacy is currently recruiting.

**Hybrid implantable cardioverter-defibrillator**

Hybrid ICD systems incorporate a combination of extra- and/or intravascular components to allow for an individualized therapy tailored to the patients’ characteristics and needs. Examples are shown in Figure 2. Expertise for each of the individual components and in case of separate modular configurations considerations of the complex interaction between the systems are primordial to provide a safe and efficient therapy. Literature on multicompartment ICDs is sparse and limited to case series and reports.

The combination of subcutaneous ICDs with a leadless cardiac pacemaker (LCP) has recently been established as a feasible combination to offer entirely leadless bradycardia therapy and high-voltage tachytherapy to a larger patient population. Animal studies demonstrated LCPs can also afford ATP delivery commanded by an implanted subcutaneous ICD and clinical applications for modular cardiac rhythm management systems with integrated wireless inter-device nearfield communication are under investigation. These systems may be further complemented by a WiSE-CRT (wireless stimulation endocardially) capable of delivering wireless LV endocardial pacing to provide completely wireless cardiac resynchronization therapy. Particular attention is required to confirm appropriate S-ICD sensing in the context of changing QRS morphologies due to breakthrough conduction, fusion, and pseudo-fusion during pacing. Re-confirmation of acceptable S-ICD sensing at the time of replacement of the original LCP is essential but limited by the stiff large-sized femoral delivery tools for LCP allowing only for supine testing prior to definitive deployment.
Transvenous ICD systems may be combined with the above-mentioned WISE-CRT or complemented by a surgically inserted LV lead to provide CRT if transvenous insertion failed. Large comparative studies for surgically vs. percutaneously placed LV pacing lead insertion for CRT have shown similar outcomes and rates of reverse ventricular remodeling for the two approaches. Extra-pleural and epicardial defibrillator coils are usually inserted together with separate epicardial pace-sense leads and may also be connected to an existing transvenous system. To reduce high DFTs refractory to non-invasive interventions, subcutaneous coils, or arrays can be incorporated in the epicardial or extra-pleural high-voltage circuit.

Wearable cardioverter/defibrillators

The WCD is a non-invasive option as a bridge-to-decision or bridge-to-recovery in acute heart failure or after an acute cardiac event with estimated high risk of ventricular arrhythmias but reasonable probability of recovery over time and with optimized medical therapy. Typical indications include acute myocarditis, peripartum- or takotsubo cardiomyopathy, or acute myocardial infarction, where the decision about the necessity of a permanent ICD should ideally be deferred. Randomized controlled trial and large registries have demonstrated the clinical effectiveness of the WCD for treating ventricular arrhythmias and also highlighted the importance of patient compliance and maximizing wearing time to achieve a clinical benefit.

Conclusion

Non-traditional ICD configurations offer important alternatives for patients at risk of sudden cardiac death due to ventricular tachyarrhythmias even in the most complex of cardiac patients and the growing range of options allow for more individualized treatment strategies. These possibilities need to be evaluated in the light of limited clinical experience and sparse long-term safety- and device performance data for the majority of these systems. Considerate patient selection and informed decision-making together with the patient is essential. Close follow-up in a centre with expertise for non-traditional systems is recommended to assure adequate device function and early identification of complications. Safety, efficacy, and lead performance of non-traditional ICDs could be further improved with development of dedicated delivery tools for minimal invasive insertion techniques and special defibrillation leads designed to meet the demands of specific coil positions. Also, the combination of high-voltage systems with leadless right- or LV pacing devices requires further clinical investigation. Dedicated modular cardiac device systems with integrated wireless inter-device communication are a promising innovative solution currently under development.

Conflict of interest: The authors have no conflict of interest to declare in relation to this manuscript.

Data availability

Data is available in a public repository that issues datasets with DOIs.

References

1. Lundqvist CB, Traykov V, Erba PA, Burri H, Nielsen JC. Borgioni MG et al. EHRA International consensus document on how to prevent, diagnose and treat cardiac implantable electronic device infections. Europace 2020;22:515–6.
2. Boczar K, Ząbek A, Habska K, Hardznia M, Dąbrowski M, Rydlewksa A et al. Venous stenosis and occlusion in the presence of endocardial leads. Adv Cardi Med 2016;25:83–91.
3. Hauser RG, Hayes DL. Increasing hazard of Sprint Fidelis implantable cardioverter-defibrillator lead failure. Heart Rhythm 2009;6:605–10.
4. Ezzat VA, Lee V, Ahsan S, Chow AW, Segal O, Rowland E et al. A systematic review of ICD complications in randomised controlled trials versus registries: is our ‘real-world’ data an underestimate? Open Heart 2015;2:e000198.
5. Hsu JC, Varosy PD, Bao H, Dewlvan TA, Curtis JP, Marcus GM. Cardiac perforation from implantable cardioverter defibrillator lead placement. Insights from the National. Gc Cardiovasc Qual Outcomes 2013;6:802–90.
6. Migliore F, Zorzi A, Bertaglia E, Leoni L, Siciliano M, De Lazzari M et al. Incidence, management and prevention of right ventricular perforation by pacemaker and implantable cardioverter defibrillator leads. Pacing Clin Electrophysiol 2014;37:1602–9.
7. Lin G, Nishimura RA, Connolly HM, Dearani JA, Sundt TM 3rd, Hayes DL. Severe symptomatic tricuspid valve regurgitation due to permanent pacemaker or implantable cardioverter-defibrillator leads. J Am Coll Cardiol 2005;45:1672–5.
8. Delling FN, Hasson ZK, Piatkowski G, Tsao CW, Rajabali A, Markson LJ et al. Tricuspid regurgitation and mortality in patients with transvenous permanent pacemaker leads. Am J Cardiol 2016;117:988–92.
9. Lin EF, Dalal D, Cheng A, Marine JE, Nazarian S, Sinha S et al. Predictors of high defibrillation threshold in the modern era. Pacing Clin Electrophysiol 2013;36:231–7.
10. Desimone CV, Friedman PA, Noheria A, Patel NA, DeSimone DC, Bider S et al. Stroke or transient ischemic attack in patients with transvenous pacemaker or defibrillator and echocardiographically detected patent foramen ovale. Circulation 2013;128:1433–41.
11. Kusumoto FM, Schoenfeld MH, Wilkoff BL, Berwald RL, Birgersdotter-Green UM, Carrillo R et al. 2017 HRS expert consensus statement on cardiovascular implantable electronic device lead management and extraction. Heart Rhythm 2017;14:e504–48.
12. Tarakji KG, Mittal S, Kennergren C, Corey R, Poole JE, Schloss E et al. Antibacterial envelope to prevent cardiac implantable device infection. N Engl J Med 2019;380:1095–903.
13. Bongiorni MG, Kennergren C, Butler C, Deharo JC, Kutarski A, Rinaldi CA et al.; ELECTRa Investigators. The European Lead Extraction ConTRolled (ELECTRa) study: a European Heart Rhythm Association (EHRA) registry of transvenous lead extraction outcomes. Eur Heart J 2017;38:2995–3005.
14. Mathur G, Stables RH, Heaven D, Ingram A, Sutton R. Permanent pacemaker implantation via the femoral vein: an alternative in cases with contraindications to the percutaneous approach. Europace 2003;5:46–9.
15. Neuzil P, Reddy V, Merkely B, Geller L, Molnar L, Bednarek J et al. Implantable intravascular defibrillator: defibrillation thresholds of an intravascular cardioverter-defibrillator compared with those of a conventional ICD in humans. Heart Rhythm 2014;11:210–5.
16. Higgins SL. Biventricular ICD placement percutaneously via the iliac Vein: report and review. J Intracard Rhythm Manag 2017;8:3784–9.
17. Elletst M4, French J. Iliac vein approach to permanent pacemaker implantation. Pacing Clin Electrophysiol 1989;12:1030–3.
18. Myung-Jin C, Jae-Sun U, Tae Hoon K, Eue-Keon C, Boyoun J, Hui-Nam P et al. Two cases of transthoracic implantation of cardiac implantable electronic device: all roads lead to Rome. Int J Arhythm 2017;18:209–14.
19. Cui K, Feng Y, Li X, Fang Y. Percutaneous transthoracic venous access for ICD implantation in a patient with Ebstein’s anomaly with ventricular tachycardia post-Glenn operation. J Cardiovasc Electrophysiol 2013;24:832–3.
20. Elayi CS, Allen CL, Leung S, Lusher S, Morales GX, Wissener M et al. Inside-out access: a new method of lead placement for patients with central venous occlusion. Heart Rhythm 2011;8:851–7.
21. Tonko JB, Black S, Rinaldi CA. “Inside-out” central venous access approach with intraclavicular exit for right sided CRT-D Implantation in bilateral brachiocephalic and superior venae cava occlusion. Clin Case Reports 2021;9:e03980.
22. Molina JE. Surgical options for endocardial lead placement when upper veins are obstructed or non-useable. J Intracard Electrophysiol 2004;11:19–54.
23. Kumar P, Baker M, Gehi AK. Comparison of single-coil and dual-coil implantable defibrillators: a meta-analysis. JACC Clin Electrophysiol 2017;3:12–9.
24. Aoukar PS, Poole JE, Johnson GW, Anderson J, Hellkamp AS, Mark DB et al. No benefit of a dual coil over a single coil ICD lead: evidence from the sudden cardiac death in heart failure trial. Heart Rhythm 2013;10:970–6.
25. Rodríguez-Maiero M, Kreidieh B, Ibarra-Cortej SH, Álvarez P, Schurmann P, Dave AS et al. Coronary venous defibrillator coil placement in patients with high defibrillation thresholds. J Arhythmia 2019;35:79–85.
26. Cooper JA, Latchapa MP, Soto GE, Garman RG, Gleva MJ, Chen J et al. The azygos defibrillator lead for elevated defibrillation thresholds: implant technique, lead stability and patient series. J Cardiovasc Electrophysiol 2008;19:1405–10.

27. Cesario D, Bhargava M, Valderrama M, Fonarow GC, Wilkoff B, Shivkumar K. Azygos vein lead implantation: a novel adjunctive technique for implantable cardioverter defibrillator placement. J Cardiovasc Electrophysiol 2004;15:116–21.

28. Nickerson KR, Jackson KP. Hemangiomas: coiled placement for high-defibrillation thresholds in a patient with a right-sided implantable cardioverter defibrillator. Pacing Clin Electrophysiol 2012;35:e10–12.

29. Markewitz A, Kaulbach H, Mattke S, Müller D, Bernutz C, Hoffmann E et al. Influence of anodal electrode position on transvenous defibrillation efficacy in humans: a prospective randomized comparison. Pacing Clin Electrophysiol 1999;22:1493–9.

30. Bar-Cohen Y, Ikoma M, Wells VJ, Saxon LA, Cesario DA, Silka MJ. Novel use of a vascular plug to anchor an azygous vein ICD lead. J Cardiovasc Electrophysiol 2010;21:109–12.

31. Van Gelder BM, Scheffer MG, Meijer A, Bracke FA. Transseptal endocardial left ventricular pacing an alternative technique for coronary sinus lead placement in cardiac resynchronization therapy. Heart Rhythm 2007;4:545–60.

32. Gradaus R, Block M, Seidl K, Brunn J, Isgro F, Hammel D et al. Comparison of implantable cardioverter-defibrillator efficacy: effect of a transvenous active can vs. a subcutaneous active can lead. J Cardiovasc Electrophysiol 2001;12:921–7.

33. Muns AF, Sakuma S, DeGroot P, Krol RB, Mathew P, Giorgiберенте I et al. Low-energy endocardial defibrillation using dual, triple, and quadruple electrode systems. Am J Cardiol 1979;47:1632–9.

34. Kempe M, Budrejko S, Dreichl L, Krolak T, Razack G, Kozlowki D. Implantation of additional subvenous array electrode reduces defibrillation threshold in ICD patients—preliminary results. AOMS 2013;3:440–4.

35. Madan N, Gaynor JW, Tanel R, Cohen M, Nicholson S, Vetter V et al. Single giga subveneous defibrillation lead and “active can”: a novel minimally invasive defibrillation configuration for implantable cardioverter-defibrillator implantation in a young child. J Thoracic Cardiovasc Surg 2003;126:1657–9.

36. Gradaus R, Hammel D, Kotthoff S, Böcker D. Non thoracotomy implantable cardioverter-defibrillator placement: use of subvenous array leads and abdominally placed ICDs in children. J Cardiovasc Electrophysiol 2001;12:356–60.

37. Boersma LV, Barr C, Knops R, Theuns D, Eckardt L, Neuzil P et al. Comparison of a vascular plug to anchor an azygous vein ICD lead. J Cardiovasc Electrophysiol 2015;27:1493–9.

38. Boersma LV, Kraniken F, Kerkhoff A, Schmidt B, Rensing S, van der Velde T et al. Azygous vein lead implantation: a novel adjunctive technique for implantable cardioverter-defibrillator placement. JACC Clin Electrophysiol 2020;6:1525–36.

39. Boersma LV, Merkely B, Neuzil P, Czerny IG, Akula DN, Timmers L et al. Therapy from a novel subvenous lead: the ASSD Study. JACC Clin Electrophysiol 2019;5:186–96.

40. Sholevad DP, Tung S, Kurianach V, Leong-ST P, Roszuk H, Engel G et al. SPACE Study Investigators. Feasibility of extracardiac pacing with a novel subvenous electrode configuration: the subvenous pacing acute clinical evaluation (SPACE) study. Heart Rhythm 2018;15:336–42.

41.https://clinicaltrials.gov/ct2/show/NCT04040680 (14 April 2021, date last accessed).

42. Tian FP, Brouwer TF, Smidt L, Kooman KM, de Groot JR, Ligon D et al. Combined leadless pacemaker and subvenous implantable defibrillator therapy: feasibility, safety and performance. Europace 2016;18:1740–7.

43. Kallaugher I, Porter B, Elliott M, Mehta V, Niederer S et al. Completely leadless cardiac resynchronization therapy systems. JACC Interventive Cardiology 2018;21:355–61.

44. Sidhu BS, Goyal J, Porter B, Elliott M, Mehta V. Non-traditional ICD configurations and insertion techniques. Non-traditional ICD configurations and insertion techniques. J Cardiothoracic Surg 2014;9:89.
73. Rickard J, Johnston DR, Price J, Tedford R, Baranowski B, Bassouny M et al. Reverse ventricular remodelling and long term survival in patients undergoing cardiac resynchronization with surgically versus percutaneously placed left ventricular pacing leads. *Heart Rhythm* 2015;12:517–23.

74. Ailawadi G, LaPar DJ, Swenson BR, Maxwell CD, Girotti ME, Bergin JD et al. Surgically placed left ventricular leads provide similar outcomes to percutaneous leads in patients with failed coronary sinus lead placement. *Heart Rhythm* 2010;7:619–25.

75. Olgin JE, Lee BK, Vittinghoff E, Morin DP, Zweibel S, Rashba E et al. Impact of wearable cardioverter-defibrillator compliance on outcomes in the VEST trial: as-treated and per protocol analyses. *J Cardiovasc Electrophysiol* 2020;31:1009–18.

76. Nguyen E, Weeda ER, Kohn CG, D’Souza BA, Russo AM, Noreika S et al. Wearable cardioverter-defibrillators for the prevention of sudden cardiac death: a meta-analysis. *J Innov Card Rhythm Manag* 2018;9:A7.

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**EP CASE EXPRESS**

**Successful bailout of refractory ventricular fibrillation originating from the moderator band using bipolar ablation in a patient with short-coupled variant of torsade de pointes**

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A 33-year-old woman was transferred to our institute with ventricular fibrillation (VF) after a few beats of torsade de pointes (TdP), which was suppressed with intravenous infusion of verapamil. The patient underwent implantable cardioverter-defibrillator implantation due to short-coupled variant of TdP. However, an electrical storm of VF recurred. Catheter ablation targeting the trigger premature ventricular contraction (PVC) with a left bundle branch block morphology and left axis deviation, where the earliest activation was recorded at the lateral aspect of the apex of the right ventricle. Neither TdP nor VF occurred at the end of the procedure. However, the VF recurred after the index procedure, and a repeat procedure was performed (Panel A). The earliest activation site was similar to that at the index procedure, 32 ms earlier than the QRS onset (Panel B). Intracardiac echocardiography showed that the ablation catheter was located at the free-wall insertion of the moderator band (Panel C). Multiple radiofrequency applications failed to suppress the PVC. Epicardial mapping revealed that the opposite site was later than the QRS onset. Bipolar ablation was attempted between the endocardial earliest activation site and the corresponding epicardial site (Panels D–F). Six bipolar radiofrequency applications at 25 W completely eliminated the PVC.

The full-length version of this report can be viewed at: https://www.escardio.org/Education/E-Learning/Clinical-cases/Electrophysiology.

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**Corrigendum**

**Corrigendum to: Successful bailout of refractory ventricular fibrillation originating from the moderator band using bipolar ablation in a patient with short-coupled variant of torsade de pointes**

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In the originally published version of this manuscript, the name of author Koichiro Yoshioka was misspelled as Koichio Yoshioka. This has now been corrected.

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