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REVIEW

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

Johanna B. Tonko [1,2,*] and Christopher A. Rinaldi[1,2]

[1]Department of Cardiology, St. Thomas' Hospital, Westminster Bridge Rd, London SE1 7EH, UK; and; and [2]Department of Cardiovascular Imaging, Arrhythmia Research Group, King's College London, School of Biomedical Engineering & Imaging Sciences, London, UK

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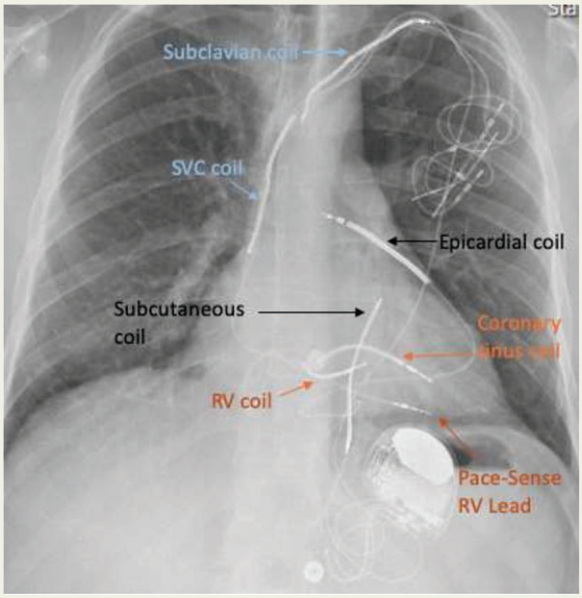
Abstract

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 bradycardiaprotection, 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.

*Corresponding author. Tel: (+44) 020 7188 7188. *E-mail address*: johanna.tonko@kcl.ac.uk

Graphical Abstract



Chest X-ray with defibrillator coils in RV, SVC, subclavian vein, coronary sinus, left parasternal subcutaneous, and epicardial space. Additional pace-sense lead in RV.

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

Key clinical message

- Transvenous implantable cardioverter-defibrillators (ICDs) inserted via the cephalic, axillary, or subclavian vein are the first-line approach for the majority of adult patients but infectious complications, intravascular lead failure, venous access restrictions, and congenital or post-surgical anatomical constraints may prevent their use.
- Dedicated subcutaneous ICD systems with parasternal coil are an established safe and efficient alternative for a selected patient group and can be combined with leadless pacemakers.
- Epicardial ICDs with off-label transvenous or subcutaneous defibrillation coils are a valuable option for patient unsuitable for transvenous or subcutaneous systems and it is feasible to incorporated them in a completely epicardial cardiac resynchronization system.
- Extra-pleural defibrillation coils in conjunction with epicardial pace-sense electrodes are a completely extravascular alternative in the paediatric population.
- Pilot studies have demonstrated feasibility of substernal defibrillator coils in adults but they are not yet commercially available.
- Defibrillator coils in the coronary sinus, azygos, or hemiazygos or subclavian vein may be used to lower unacceptably high defibrillation/fibrillation thresholds with standard transvenous ICD devices.

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 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 as 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.

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[11]. Likewise, device-related infectious events remain an important complication despite the use of preoperative antibiotics and recent demonstration of further risk reduction by the use of absorbable antibacterial envelops[12]. They account for 52.8% of indications for extraction[13]. 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/-iliacal[16,17] or trans-hepatic access[18,19] 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[20]. 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 ventricular 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.[22]

Alternative intravascular defibrillator coil positions

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

Table 1 Complications of transvenous devices

- Infection/CIED-associated endocarditis (0.6–3.4%/years[1])
- Venous occlusion/obstruction (up to 37%[2]) ± SVC syndrome
- Lead dysfunction/failure (specific leads up to 3.75%/years[3])
- Lead displacement (3.1%/16 months[4])
- Lead perforation 0.14[5]–0.3%[6] ± pericardial tamponade
- Lead-related tricuspid regurgitation associated with right heart failure[7] and increased mortality[8]
- High DFT/failed DFT (2.2%[9])
- Three-fold risk of systemic embolism in presence of intracardiac shunt[10]
- Risks of extraction (major complication in 0.2–1.8%[11])
- Overall ICD complication rate in RCTs 9.1%/16 months[4]

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

		Advantage	*Disadvantage*
Alternative venous access options[a]	Transhepatic Transfemoral/iliacal	• Percutaneous minimal invasive • Independent of upper thoracic vein patency • Allows for standard transvenous lead position in right ventricle providing tachytherapy and bradytherapy	• 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]) • Inferior vena cava obstruction/occlusion • Higher bleeding risk at access site/hepatic injury
	Inside out venous access	• Percutaneous minimal invasive • Allows for pectoral generator and standard RV lead position providing tachytherapy and bradytherapy • Dedicated equipment available	• Experience mainly for placement of dialysis catheters and with right-sided exits with less favourable shocking vector for ICDs • Infraclavicular exit technically challenging and risk of damaging the great arteries • Requires patent femoral access
	Transthoracic transatrial	• Independent of venous patency and vessel size • Standard RV lead position, providing tachytherapy and bradytherapy	• Thoracotomy required, general anaesthesia • Limited literature on durability, safety/efficacity • Paediatric case series/reports only
• Alternative intravascular HV coil positions[b] • *Historically*	Coronary sinus (CS)	• Percutaneous insertion • Independent of tricuspid valve abnormalities (stenosis, replacement/repair) • Shown to be effective in reduction of high DFT • Bulk of lead body protected by rib cage	• Requires sufficiently large vascular calibre of ventricular coronary sinus branch • Delivery of CRT via CS coil unreliable • 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
	Hemi-/azygos vein Left subclavian vein		• Difficult access for azygos/hemi-azygos vein • Require separate pace-sense lead (transvenous to RV or CS or epicardial/pericardial) • Higher risk of lead displacement • May require vascular plug to anchor lead
	Percutaneous intravascular cardioverter defibrillator[15]	• *Similar DFT as conventional ICD* • *No device pocket* • *Ease of insertion*	• *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.

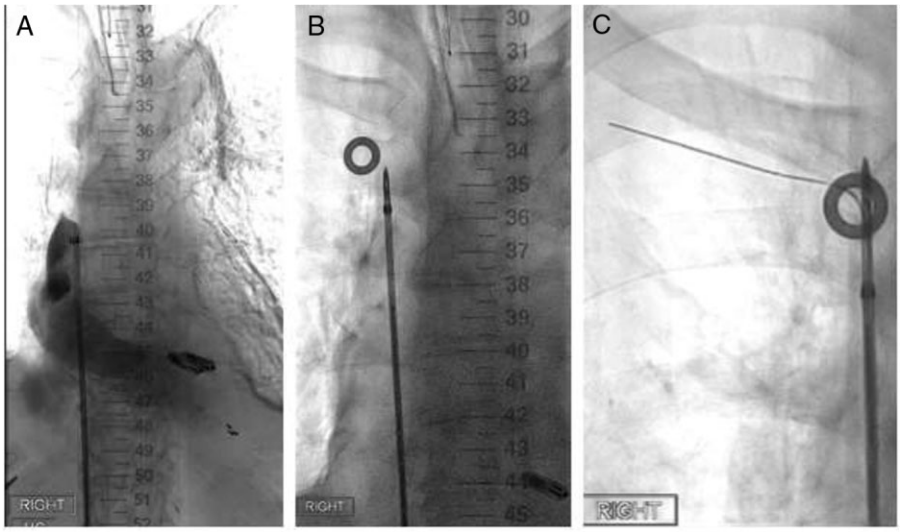


Figure 1 Inside-out central venous access with right infraclavicular exit in superior vena cava occlusion (adapted from Ref.[21]). (*A*) Venogram via femoral working sheath demonstrates occluded SVC. (*B*) Inside-out venous access kit with needle guide puncturing through occluded vein segment and (*C*) guide wire exiting at site of radiopaque skin marker inferior to right clavicula.

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.[23,24] 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[25], azygos vein[26,27], hemi-azygos vein (with right-sided generator)[28] or left subclavian veins[29] 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.[30]

Coronary sinusdefibrillator coils may also be offered to patients with tricuspid valve abnormalities (including mechanical valve prothesis 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.[25] 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.

Trans-septal access and placement of leads into the LV cavity has been described for pacing leads only[31], 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[32] and patches[33] 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[34]. 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[35] and that in children subcutaneous array leads with an active can could safely achieve defibrillation even in the absence of a transvenous device[36].

Table 3 Summary extracardiac ICD configurations

Configuration		Advantages	Disadvantages	Pace/sense lead[a]	Evidence[b]
Subcutaneous	(1) Subcutaneous ICD system (Boston Scientific S-ICD™ system)—parasternal tripolar lead	• Entirely extravascular • Lower risk of systemic infection • Ease and predictability of implant • No risk of embolic events • Lower risks of extraction if required • MRI conditional	• No bradycardia protection or cardiac resynchronization • No anti-tachycardia pacing • Higher shock energy requirement • Large pulse generator size • High % of failed S-ICD screening • Limited diagnostic features • 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 • Suitable also in small children • Bailout option in high DFT for endovascular systems	• Unsuitable in severe obesity • Separate pace-sense lead required • If used in isolation higher DFT as transvenous/epicardial systems	Epi-or pericardial Transvenous (RV and/or LV)	• Prospective randomized trials
Epicardial/pericardial	(1) Off label use of transvenous/subcutaneous coils (2) *Patches (historical)*	• Independent of vascular continuity/venous patency • No thromboembolic risk • Lower risk for infection • Minimal invasive insertion techniques (sub-xiphoid, VATS) available	• Higher periprocedural morbidity if sternotomy/thoracotomy approach • Specific risks associated with epicardial position (see *Table 4*) • Higher rates of lead failure • Limited long-term experience with defibrillation coils • Separate pace-sense lead required • Not MRI conditional	• Epi- or peri- cardial • Transvenous (RV and/or LV)	• Coils: case series/case reports • *Patches: prospective comparative studies*
Substernal	Coil in substernal space in anterior mediastinum	• Extravascular • Lead body protected by sternum • Minimal invasive subxiphoid approach • Lower shock energy requirement than subcutaneous ICDs	• No long-term data • Not commercially available	• Not required	• Feasibility studies/case reports • *Prospective open-label multicentre trial ongoing*

Continued

Table 3 *Continued*

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

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

[a]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).

[b]Main text for respective references.

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[37] and randomized trial[38] 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)[39] 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[40]) 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[41] and 15% for 2 vectors[42] 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[43] 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.[44]

Table 4 Complications of epicardial ICD devices

- Coronary artery compression (5.5% in children/CHD[52]).
- Constrictive pericarditis/pericardial adhesions.[53]
- Erosion in intrathoracic organs with broncho-/oesophageal-pericardial fistulas.[54]
- Cardiac strangulation (mismatch between lead length and heart size, 2.3%[55] in paediatric patients).
- Proarrhythmogenic if pacing in proximity to scar.[56]
- 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.

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.[45]

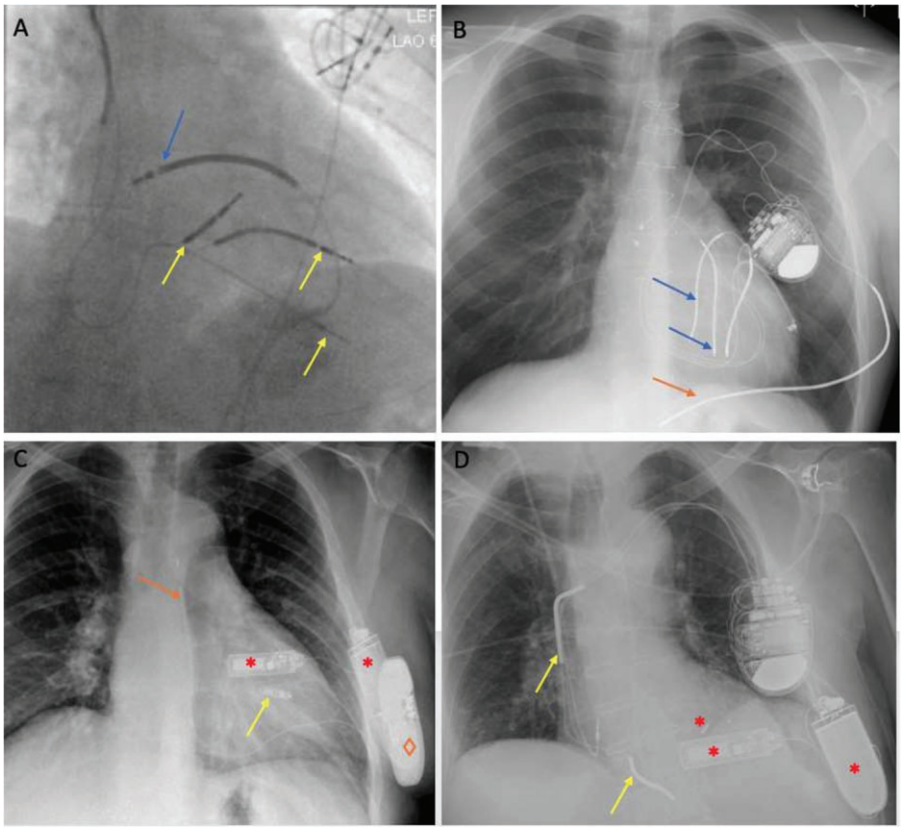


Figure 2 Examples for hybrid ICD configurations. (*A*) Transvenous dual-coil ICD including coronary sinus coil and pace-sense leads (yellow arrows, two abandoned, one tunnelled to abdominal generator) with epicardial defibrillator coil (blue arrow). (*B*) Epicardial ICD with two dual-coil HV leads (blue 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 hearts 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.[46]

For epicardial pacing leads acceptable long-term lead performances have been described[47–49]; 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[50]). 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 efficiency and safety of epicardial ICDs employing standard transvenous or subcutaneous coils.[51] Minimal invasive insertion techniques with lower peri-operative morbidity have further contributed to their 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.[57,58]

Extra-pleural implantable cardioverter-defibrillator

Paediatric and adolescent population case series[59–61] 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 efficiency 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[59].

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 defibrillator 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[62] or the use of standard subcutaneous coils with integrated sensing electrodes[63]. 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[64] allowing for smaller generator sizes. First-In-Human pilot studies yielded encouraging results[65,66] 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 [67].

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.[68]

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 multicomponent 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 bradytherapy and high-voltage tachytherapy to a larger patient population.[69] Animal studies demonstrated LCPs can also afford ATP delivery commanded by an implanted subcutaneous ICD[70] and clinical applications for modular cardiac rhythm management systems with integrated wireless inter-device nearfield communication are under investigation.[71] 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.[72] 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 remodelling for the two approaches[73,74].

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.[75,76]

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.

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EP CASE EXPRESS

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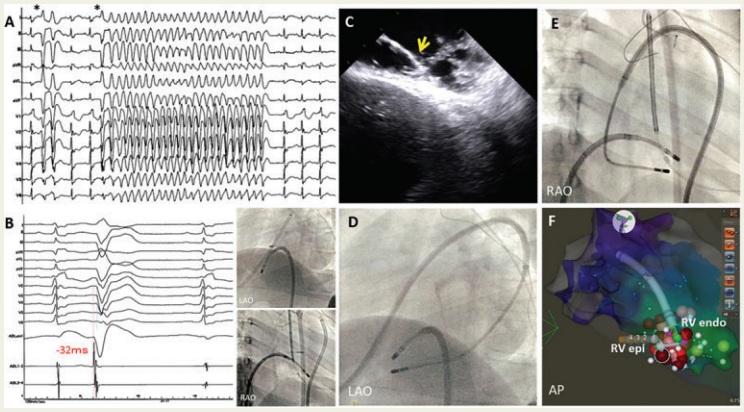
Successful bailout of refractory ventricular fibrillation originating from the moderator band using bipolar ablation in a patient with short-coupled variant of torsade de pointes

Atsuhiko Yagishita [1]*, Masahiko Goya[2], Susumu Sakama[1], Mari Amino[1], Yuji Ikari [1], and Koichiro Yoshioka[1]

[1]Department of Cardiology, Tokai University, Shimokasuya 143, Isehara, Kanagawa 259-1193, Japan; and [2]Department of Cardiovascular Medicine, Tokyo Medical and Dental University, Tokyo, Japan

* Corresponding author. Tel: +81 463 93 1121; fax: +81 463 93 6679. *E-mail address*: ayagishita@tsc.u-tokai.ac.jp



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.

Corrigendum

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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.