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Extravascular ICDs in Portugal: From concept to clinical reality.

Cardioversores-desfibrilhadores implantáveis extravasculares em Portugal: do conceito à realidade clínica

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Technology designed to fill a clinical gap

Conventional transvenous Implantable cardioverter-defibrillators (ICDs) remain the gold standard for sudden cardiac death (SCD)prevention; their long-term limitations (lead failure, venous occlusion, systemic infection and difficult extractions) are well documented, especially in younger patients expected to carry devices for decades.[1] The development of the entirely subcutaneous ICD (S-ICD) was an important response to these concerns, eliminating transvenous leads and lowering systemic infection risk.[2] However, the S-ICD cannot deliver anti-tachycardia pacing (ATP) or provide meaningful bradycardia support. It may also require relatively high defibrillation energies.[2]

The extravascular ICD (EV-ICD) was conceived to combine the best of both worlds: a completely extravascular lead placed retrosternally, avoiding the venous system, but able to deliver cardioversion, defibrillation, ATP and limited bradycardia pacing.[4-7] Early international studies, including the Pivotal trial and subsequent analyses, have shown high implant success, acceptable defibrillation thresholds (DFTs) and promising safety and quality-of-life profiles.[5–9] The report by Lousinha et al. brings this innovation from global trials into Portuguese routine practice.[3]

Who are the early Portuguese EV-ICD recipients?

The preferential indication for this novel device is the first important question. In this setting, the cohort described by the authors is highly representative of the population for whom an extravascular solution is most appealing: young patients (mean age 36 years) with inherited cardiomyopathies and channelopathies, preserved or mildly reduced left ventricular function, and no indication for permanent pacing or resynchronization.[3] Hypertrophic cardiomyopathy, non-dilated left-ventricular cardiomyopathy, dilated cardiomyopathy, Brugada syndrome, polymorphic ventricular tachycardia and arrhythmogenic right ventricular cardiomyopathy are all conditions associated with lifelong SCD risk and substantial cumulative device exposure.[2, 3]

In such patients, repeated transvenous lead revisions over decades can be particularly problematic, and the possibility of an entirely extravascular system with ATP is conceptually very attractive. The authors applied guideline-based indications for ICD therapy according to the 2022 ESC ventricular arrhythmia guidelines,[10] while excluding patients with pacing-

dependent bradyarrhythmias or resynchronization indications, an approach fully consistent with current recommendations and device capabilities.

Procedural workflow: Multidisciplinary, efficient and reproducible

One of the strengths of this report is its detailed description of workflow and team composition.[3] Implantation was performed in a standard electrophysiology laboratory under general anesthesia by a tandem of electrophysiologist and cardiac surgeon, supported by anesthesiology, nursing, and radiology staff. This multidisciplinary model mirrors that used in first-in-human and Pivotal investigations and may be particularly important in the early learning curve.[4–7]

Although it was a new procedure in both centers, the mean "skin-to-skin" time was just over one hour and fluoroscopy time under four minutes. These figures compare favorably with the Pivotal trial and underline how rapidly the technique can be mastered.[5] Importantly, no conversions to transvenous or subcutaneous systems were required, and there were no significant acute complications such as bleeding, pneumothorax, cardiac injury or pocket hematoma.[3]

Defibrillation testing was uniformly successful, with 10 of 11 patients defibrillated at 30 J and only one requiring 40 J, again fully in line with the literature data, where more than 98% of patients are successfully converted with ≤40 J.[5,6] These results reinforce the concept that the retrosternal vector provides an efficient current pathway across both ventricles at lower energies than those typically required by S-ICD systems.[3,5]

Early safety signals and patient experience

The absence of infection, lead dislodgement or early system revisions in this initial Portuguese experience is reassuring and consistent with the extravascular design, which avoids intravascular material.[2,3,5] Pain was frequent but manageable: about one-third of patients reported significant retrosternal discomfort in the first 24 hours, requiring opioid analgesia.[3] Similar experiences have been described in early EV-ICD cohorts and tend to improve with the learning curve, as operators refine tunneling technique and pocket creation.[4–7]

Radiographic follow-up showed excellent lead stability, with only minor posterior or rightward tilt in a few cases that did not affect sensing or impedance.[3] The absence of pocket erosion, systemic infection or the need for extraction in this very short follow-up is encouraging, though longer-term data remain crucial.[3]

Beyond hard endpoints, patient-reported outcomes are increasingly acknowledged as being central in device evaluation. In the Pivotal study, EV-ICD recipients reported favorable quality of life and high device acceptance. It will be important for future series to include standardized quality-of-life instruments, especially in young, active patients for whom device visibility, comfort and activity restrictions are highly relevant.

Inappropriate shocks: A familiar yet addressable challenge

The authors also report in this preliminary experience on the occurrence of two inappropriate shocks (18%) within three months: one triggered by rapid sinus tachycardia in a non-beta-

blocked patient, and one due to myopotential oversensing.[3] This rate is higher than the 9.7% reported over a median 10.6-month follow-up in the Pivotal trial,[5] but the difference must be interpreted cautiously given the small numbers and the particular composition of the cohort: young patients with inherited diseases, high adrenergic tone and preserved ejection fraction. These patients have exactly the same profile that is traditionally associated with more supraventricular events and oversensing issues.[11,12]

The detailed episode analyses are instructive. In the first case, sinus tachycardia accelerated into the fast VT zone and, in the absence of beta-blockade, mimicked monomorphic VT, triggering ATP and shock.[3] This underscores a principle already familiar from S-ICD and transvenous ICD programming trials: generous rate cut-offs, long detection times and systematic use of beta-blockers can dramatically reduce inappropriate therapy without compromising safety.[11]

The second case, involving myopotential oversensing, highlights an area of active learning for EV-ICDs.[3] Retrosternal sensing vectors differ from both endocardial and subcutaneous configurations, and conventional provocative maneuvers may not reliably reproduce artifacts. Recent large-scale analyses of EV-ICD sensing and detection have identified several new discrimination features to mitigate non-cardiac oversensing,[12] while dedicated clinical series have proposed structured troubleshooting algorithms.[13] Applying these insights prospectively together with careful pre-implant assessment of body habitus, muscular activity patterns and occupational demands may help reduce such events.

Programming matters as much as technology

If one overarching message emerges from the experience of Lousinha et al., it is that programming strategies are Pivotal for the success of EV-ICD therapy.[3] At least one of the inappropriate therapies described would probably have been avoided by a higher VT cut-off. This parallels the paradigm shift produced by trials such as MADIT-RIT and UNTOUCHED, which showed that “shock-sparing” programming with higher rate thresholds and prolonged detection intervals can simultaneously reduce inappropriate interventions and improve survival.[11]

For the EV-ICD, this means considering:

- Higher VT/FVT detection zones in young, non-ischemic patients
- Systematic use of ATP only when monomorphic VT is genuinely expected
- Liberal application of morphology discrimination and non-cardiac signal filters[12,13]
- Aggressive rate control with beta-blockers in patients prone to adrenergic surges

As experience grows, consensus programming schemes, similar to those developed for S-ICD systems will be essential to standardize care and facilitate benchmarking between centers.[10,11]

Where does the EV-ICD fit in the Portuguese sudden cardiac death strategy?

The Portuguese Strategic Plan for Cardiovascular Health identifies SCD prevention, equitable access to ICD therapy and health care professional education as national priorities.[14] The early adoption of EV-ICD technology by Portuguese centers aligns closely with these goals and positions Portugal within the group of European countries actively exploring innovative extravascular solutions.

From a practical standpoint, the EV-ICD should not be viewed as a replacement for either transvenous ICDs or S-ICDs, but rather as a complementary option.[2,11] In patients with pacing or resynchronization indications, transvenous or leadless-plus-transvenous strategies will remain necessary. In young patients with no need for pacing but unfavorable S-ICD screening or strong preference for ATP, the EV-ICD emerges as an especially attractive alternative.[4–7] EV-ICD use in scenarios such as recurrent pocket erosion or after transvenous extraction further extend its potential indications.

Wider adoption will require structured training for electrophysiologists and cardiac surgeons, clear referral pathways, and robust local and national registries capable of tracking long-term outcomes, complications, patient-reported measures and cost-effectiveness. Lessons from S-ICD implementation over the last 15 years suggest that early concentration of expertise in a limited number of high-volume centers can accelerate the learning curve while maintaining safety.[11]

Looking ahead: Consolidating evidence and refining practice

The work by Lousinha et al. is, by design, an early experience: 11 patients, three months of follow-up and a focus on feasibility and acute performance.[3] Yet such "first-wave" data are invaluable. They reassure clinicians that EV-ICD implantation is doable in standard electrophysiology laboratories, without systematic need for sternotomy or surgical theaters; they identify real-world pain points, in terms of post-operative discomfort, and in terms of inappropriate shocks; and they offer practical hints for patient selection and programming that will inform subsequent adopters.

Future research priorities on EV-ICD should also include:

- Prospective multicenter registries capturing all EV-ICD implants
- Longer-term follow-up of lead performance, battery longevity and extraction experience
- Systematic assessment of quality of life, return to work and sports participation
- Comparative effectiveness analyses versus S-ICD and transvenous systems in key subgroups such as hypertrophic cardiomyopathy or Brugada syndrome
- Evaluation of structured training pathways and simulation-based curricula for operators.

Extravascular ICD technology represents a logical and exciting step in the evolution of SCD prevention: a system that respects the vasculature, offers selective pacing capabilities and can be implanted with high procedural success. International literature data have already demonstrated its feasibility and safety; the report by Lousinha et al. shows that these results are now a reality in Portuguese real-world practice and within the framework of national cardiovascular health priorities.

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