

# Epicardial vs. transvenous implantable cardioverter defibrillators in children

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## Aims

The implantable cardioverter defibrillator (ICD) has been increasingly used in children. Both epicardial and transvenous approaches are used, with controversy regarding the best option with no specific recommendations. We aimed to compare outcomes associated with epicardial vs. transvenous ICDs in children.

## Methods and results

Data were analysed from a retrospective study including all patients <18-year-old implanted with an ICD in a tertiary centre from 2003 to 2021. Outcomes were compared between epicardial and transvenous ICDs. A total of 122 children with an ICD (mean age  $11.5 \pm 3.8$  years, 57.4% males) were enrolled, with 84 (64.1%) epicardial ICDs and 38 (29.0%) transvenous ICDs. Early (<30 days) ICD-related complications were reported in 17 (20.2%) patients with an epicardial ICD vs. 0 (0.0%) with a transvenous ICD ( $P = 0.002$ ). Over a mean follow-up of  $4.8 \pm 4.0$  years, 25 (29.8%) patients with an epicardial ICD and 9 (23.7%) patients with a transvenous ICD experienced at least one late ICD-related complication [hazard ratio (HR) 1.8, 95% confidence interval (CI) 0.8–4.0]. Implantable cardioverter defibrillator lead dysfunction occurred in 19 (22.6%) patients with an epicardial ICD vs. 3 (7.9%) with a transvenous ICD (HR 5.7, 95% CI 1.3–24.5) and was associated with a higher incidence of ICD-related reintervention (HR 3.0, 95% CI 1.3–7.0). After considering potential confounders, especially age and weight at implantation, this association was no longer significant ( $P = 0.112$ ). The freedom from ICD lead dysfunction was greater in patients with pleural coils than in those with epicardial coils (HR 0.38, 95% CI 0.15–0.96).

## Conclusion

In children, after a consideration of patient characteristics at implantation, the burden of complications and ICD lead dysfunction appears to be similar in patients with epicardial and transvenous devices. Pleural coils seem to be associated with better outcomes than epicardial coils in this population.

## Clinical Trial Registration

NCT05349162.

## Keywords

Paediatric • Implantable cardioverter defibrillator • Ventricular arrhythmia • Sudden death • Congenital heart disease

## What's new?

- The higher incidence of implantable cardioverter defibrillator (ICD) lead dysfunction with epicardial devices, compared with transvenous ICD, is driven by a preferential use in youngest patients.
- Pleural coils seem to be associated with better outcomes than epicardial coils in children.

## Introduction

The implantable cardioverter defibrillator (ICD) is highly effective in preventing arrhythmic death in high-risk patients and has been increasingly used in children with the extension towards primary prevention of sudden cardiac death (SCD).<sup>1,2</sup> However, the burden of ICD-related complications is considerable in this fragile population. Both epicardial and transvenous approaches are used,<sup>3</sup> but the best option remains

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controversial, and no specific recommendations are provided in international guidelines.<sup>4,5</sup> While a few studies compared epicardial and transvenous systems, they included heterogeneous populations that also comprised adults, with results difficult to translate into clinical practice for paediatric patients.<sup>6–8</sup> Moreover, the proportion of epicardial systems was relatively modest, and outcomes associated with the different surgical techniques, particularly regarding coil positioning, have been poorly studied so far.<sup>8–13</sup>

In this study, through a large and purely paediatric population of children implanted with ICDs from a tertiary centre, we aimed to compare outcomes associated with epicardial vs. transvenous ICDs in children and to assess the impact of the surgical approach in epicardial systems.

## Methods

### Study population and settings

This observational study included all patients <18-year-old implanted with an ICD at Necker Hospital, Paris, France, from January 2003 to January 2021 (NCT05349162). Patients with subcutaneous-ICD (S-ICD) were not considered. Necker Hospital is a national referral centre in paediatric cardiology and surgery and includes multidisciplinary teams with cardiologists, interventional cardiologists, surgeons, imaging specialists, anaesthesiologists, and electrophysiologists specifically trained in paediatric cardiology. In this tertiary centre, all patients are systematically gathered in phenotype- and intervention-based databases since first evaluation to ensure a comprehensive collection of cases over time.

Study data were centralized, collected, and managed using REDCap electronic data capture tools hosted at the Cardiovascular Epidemiology Unit of the Paris Cardiovascular Research Center (Inserm 970, European Georges Pompidou Hospital, Paris, France).<sup>14</sup> This study complied with the French data protection committee (Commission Nationale Informatique et Liberté, CNIL, MR-004 no. 2021 0727164137), was approved by the institutional review board, and adhered to Helsinki Declaration as revised in 2013. Written informed consent was obtained from all patients before ICD implantation.

### Collected data

Baseline (at ICD implantation) information included demographic characteristics, medical history including underlying heart disease, family history of SCD, and indication for ICD (primary vs. secondary prevention). Secondary prevention was defined as ICD implantation after sustained ventricular tachycardia (VT), ventricular fibrillation (VF), or aborted cardiac arrest. In patients with structural heart disease, imaging data (echocardiography ± cardiac magnetic resonance imaging) were also analysed, as well as details on previous cardiac surgeries (where appropriate). Patients with a congenital heart disease (CHD) were classified according to last AHA/ACC and ESC classifications.<sup>15,16</sup>

Comprehensive data were also collected regarding the type of device implanted (single vs. dual chamber, cardiac resynchronization therapy, epicardial).

### Surgical techniques

The surgical techniques differed based on the surgeon's preference and whether indication for surgical ICD implantation was isolated or whether the patient required an associated open-heart surgery through a midline sternotomy, cardiopulmonary bypass, and aortic cross-clamping. A defibrillation test was performed at the end of implantation in all patients (transvenous and epicardial devices) to ensure proper sensing and defibrillation capacities of the system, but the defibrillation threshold was not systematically measured.

### Implantable cardioverter defibrillator implantation with a pleural coil

By using a subxiphoid incision or partial inferior sternotomy, a sutured-on lead was implanted on the right atrium and either a sutured-on or screwed-in lead was implanted on the apex of the left ventricle. A second incision was then performed in the first left intercostal space in order to insert a tunnelled coil behind the ribs right above the pleura. The ICD was then inserted in a retromuscular abdominal pocket.

### Implantable cardioverter defibrillator implantation with an epicardial coil

This approach was mainly used after an open-heart surgery when the aortic clamp has been removed. A sutured-on lead was implanted on the right atrium and a sutured-on or screwed-in lead was fixed on the apex of the left ventricle. An epicardial coil was then sutured all along the right ventricular anterior wall with utmost caution so that the coronary arteries and the epicardial areas are protected from potential postoperative fibrosis and scarring due to heterologous or synthetic material implantation (mainly for infundibular patch enlargement in modified Konno procedures in severe obstructive hypertrophic cardiomyopathy). Depending on the age and size of the patient, the indication, the surgical procedure performed previously, and the surgeon's preferences, the ICD was inserted in a diaphragmatic pocket below the heart (with only one coil implantation) or in an abdominal retromuscular pocket with a second coil implantation on the right ventricle inferior wall ( $n = 5$  patients) (Figure 1).

### Outcomes

During follow-up, all ICD-related complications and reinterventions were recorded. Implantable cardioverter defibrillator complications were divided into early (<30 days after implantation) and late (>30 days) complications and included pocket haematoma, pneumothorax, pericardial effusion, device infection, lead dysfunction, and inappropriate ICD shocks. Appropriate ICD therapies (ICD shock or anti-tachycardia pacing) were also collected. Implantable cardioverter defibrillator programming was left to the discretion of the managing physician. Other outcomes included heart transplantation and vital status with cause of death (where appropriate).

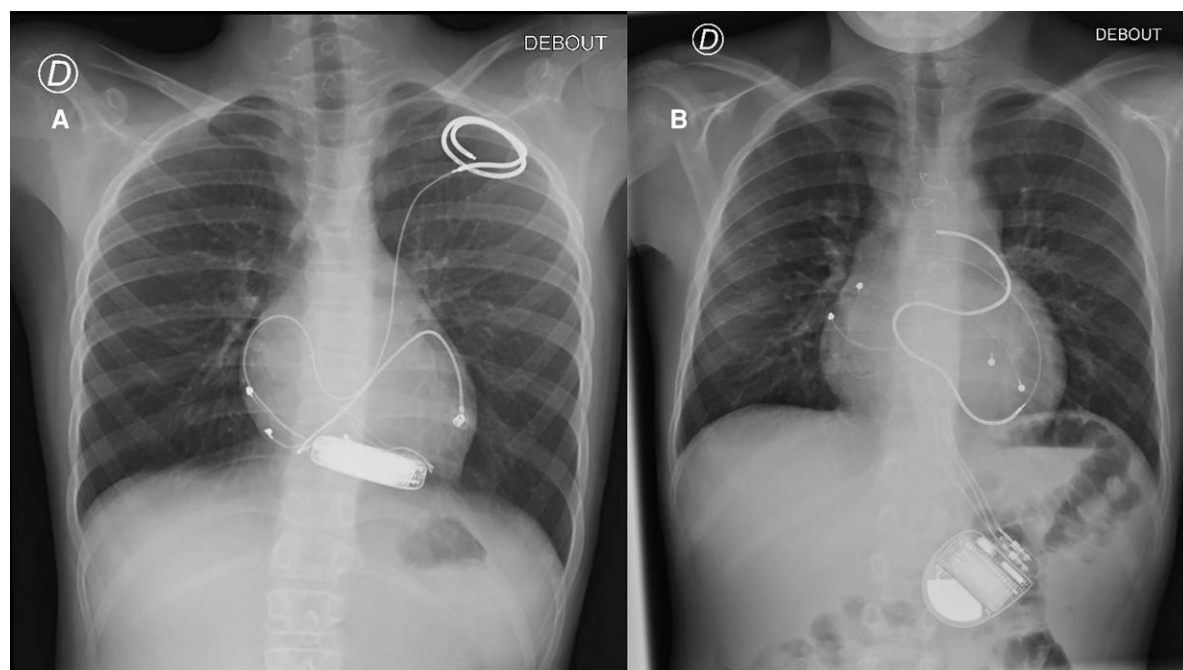
### Statistical analysis

This report was prepared in compliance with the STROBE checklist for observational studies.<sup>17</sup> Categorical data were reported as numbers and percentages. Continuous data were reported as mean ± standard deviation or median and interquartile range (IQR) for normally and non-normally distributed data, respectively. Comparisons used the  $\chi^2$  or Fisher's exact test for categorical variables and Student's *t*-test or Mann–Whitney–Wilcoxon test, when appropriate, for continuous variables. The primary time to event endpoint was the time from ICD implantation to first ICD-related complication or reintervention. Censoring occurred in the event of loss to follow-up, heart transplantation, death, or switch of ICD system type. Univariate and multivariate Cox proportional hazard models were used to identify factors associated with ICD-related complications and to compare outcomes of transvenous vs. epicardial ICDs. Proportional hazards assumptions were checked for all variables (Schoenfeld residuals) and non-linearity for continuous variable (Martingale residuals) with the use of appropriate functional forms. Survival curves were plotted by the Kaplan–Meier method. A two-tailed *P*-value of <0.05 was considered statistically significant. All data were analysed using the R software, version 3.6.3 (R Project for Statistical Computing, Vienna, Austria).

## Results

### Population

Among a total of 131 children <18 years with an ICD, after exclusion of 9 patients implanted with an S-ICD, 122 patients [mean age  $11.5 \pm 3.8$  years, 70 (57.4%) males] were analysed. The number of patients among different age and weight ranges is displayed in Figure 2. Epicardial ICDs accounted for almost all implantations before the age of 8 or under 25 kg, and the proportion of transvenous ICDs remained very low before the age of 14. After the age of 14, epicardial and transvenous devices accounted for approximately half of the implantations. The main underlying heart diseases were cardiomyopathies in 74 (56.5%) patients, cardiac channelopathies in 40 (30.5%), and CHDs in 4 (3.1%). The detail of heart diseases according to the type of ICD implanted is provided in Figure 3. The distribution of the different underlying heart diseases was comparable in both groups. Patients were implanted for primary prevention in 65 (53.3%) and for secondary prevention in 57 (46.7%). Cardiomyopathies were the main underlying heart disease in



**Figure 1** Examples of epicardial ICDs. Epicardial ICDs with a defibrillation coil inserted in the pleural position (A) and in the epicardial position on the anterior wall of the right ventricle (B). ICD, implantable cardioverter defibrillator.

primary prevention ( $n = 52$ , 78%), whereas channelopathies were the main indication in secondary prevention ( $n = 30$ , 46%).

### Type of implantable cardioverter defibrillators implanted

Overall, 84 (64.1%) patients had an epicardial ICD and 38 (29.0%) a transvenous ICD. The main characteristics of patients at implantation according to the type of device implanted are summarized in Table 1. Compared with patients with transvenous ICD, those with epicardial ICD were younger ( $13.3 \pm 3.1$  vs.  $10.8 \pm 2.9$  years,  $P < 0.001$ ) with a lower mean weight ( $45.5 \pm 13.7$  vs.  $37.7 \pm 16.5$  kg,  $P = 0.016$ ), they were more frequently implanted for secondary prevention (28.9 vs. 64.3%,  $P = 0.001$ ), and they had a higher median (IQR) left ventricular ejection fraction [60 (45–60) vs. 60 (60–68) %,  $P = 0.001$ ]. The proportion of single-chamber devices was also lower (73.3 vs. 14.3%,  $P < 0.001$ ) in patients with epicardial ICD.

Among patients implanted with an epicardial ICD, the coil was inserted in the pleural position in 41 of them (51.3%) and in epicardial position in 40 (49.4%) (location unknown in 3). Epicardial coil positioning included the anterior wall of the right ventricle ( $n = 34$ ), the pulmonary artery trunk ( $n = 4$ ), and the pericardial space ( $n = 2$ ). Screwed-in ventricular sensing/pacing leads were used in 38 (47.5%) patients, whereas sutured-on leads were used in 42 (52.5%) (lead type unknown in 4). The ICD pocket was between the heart and the diaphragm in 68 patients (84.0%) and abdominal in 13 (18.8%) (unknown in 3).

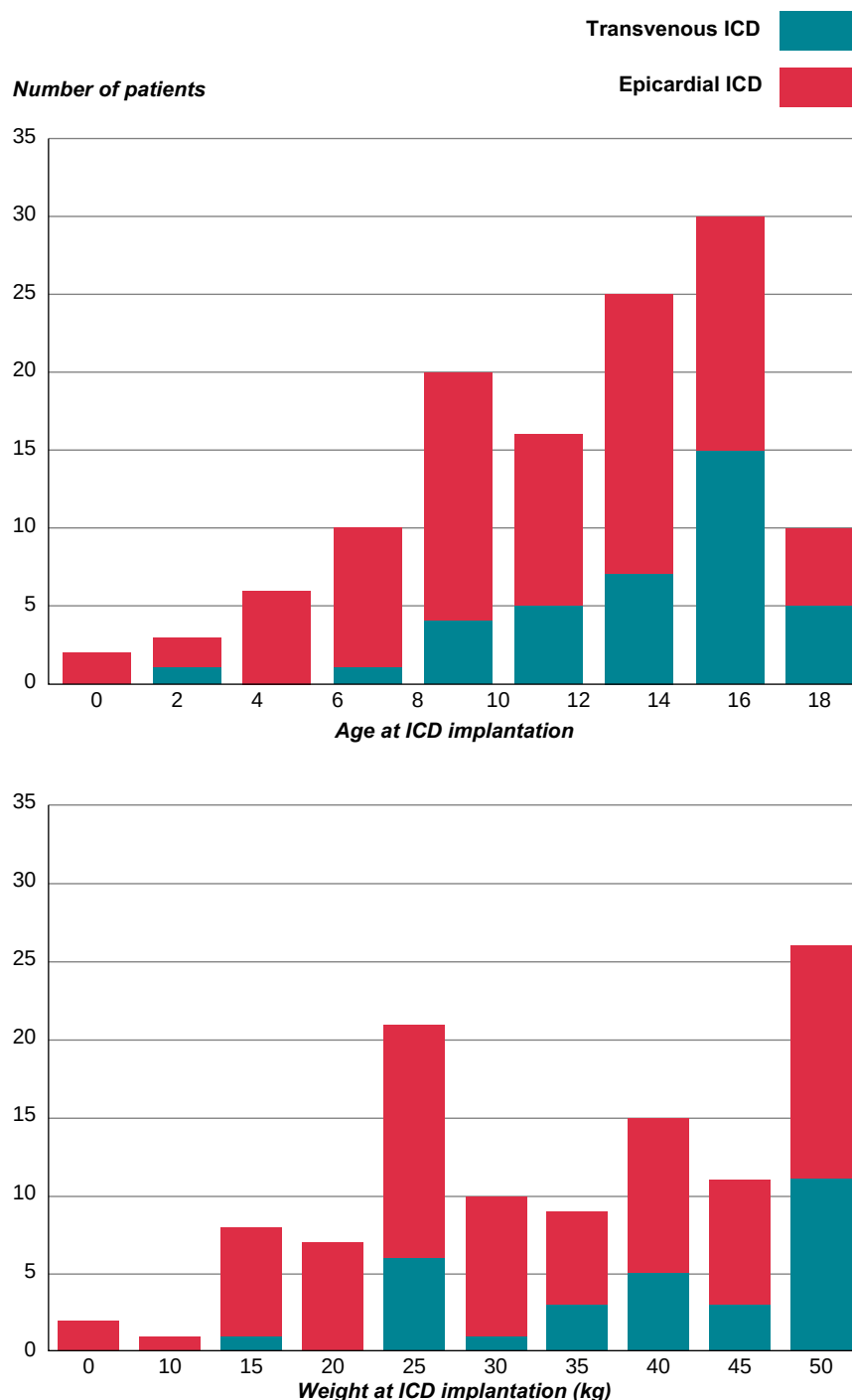
### Implantable cardioverter defibrillator-related complications

Early (<30 days) ICD-related complications were reported in 17 (20.2%) patients with an epicardial ICD vs. 0 (0.0%) patient with a transvenous ICD ( $P = 0.002$ ). The main early complications were pleural

effusions ( $n = 6$ ), pneumothorax ( $n = 4$ ), pericardial effusion or tamponade ( $n = 3$ ), early coil dysfunction ( $n = 1$ ), endocarditis (ICD pocket infection resulting in bacteraemia and endocarditis,  $n = 1$ ), pneumonia ( $n = 1$ ), and death ( $n = 1$ ). Among those 17 patients with an early complication, 5 (29.4%) had an ICD implantation during a modified Konno surgery for obstructive hypertrophic cardiomyopathy. When patients with concomitant cardiac surgery ( $n = 22$ ) were not considered, an early ICD-related complication was reported in 12 (19.4%) patients. Two early deaths were reported: one cardiac arrest the day after ICD implantation related to a slow VT that degenerated to asystole in a patient with severe restrictive cardiomyopathy (considered as ICD-related complication) and one postoperative cardiogenic shock with multiple organ failure was reported after a modified Konno surgery.

Over a mean follow-up of  $4.8 \pm 4.0$  years ( $4.5 \pm 3.5$  years in patients with an epicardial ICD vs.  $5.5 \pm 5.0$  years in patients with a transvenous ICD,  $P = 0.259$ ), 25 (29.8%) patients with an epicardial ICD and 9 (23.7%) patients with a transvenous ICD experienced at least one late ICD-related complication [HR 1.8, 95% confidence interval (CI) 0.8–4.0,  $P = 0.153$ , Figure 4]. The detail of these late complications is presented in Table 2. An ICD lead dysfunction occurred in 19 (22.6%) patients with an epicardial ICD vs. 3 (7.9%) patients with a transvenous ICD (HR 5.7, 95% CI 1.3–24.5,  $P = 0.021$ ) and was associated with a higher incidence of ICD-related reintervention (HR 3.0, 95% CI 1.3–7.0,  $P = 0.011$ ). The corresponding 5-year survival rates without ICD lead dysfunction were 76.8 vs. 100.0% in patients with epicardial ICD vs. transvenous ICD. The 5-year survival rates without reintervention were 78.7 vs. 82.4%, respectively. Among patients with an epicardial ICD, the freedom from ICD lead dysfunction was greater in patients with pleural coils than in those with epicardial coils [7 (17.1%) vs. 12 (30.8%) dysfunctions, HR 0.38, 95% CI 0.15–0.96,  $P = 0.041$ , Figure 5].

Age (HR 0.84 per year increment, 95% CI 0.75–0.95,  $P = 0.004$ ) and weight (HR 0.96 per kg increment, 95% CI 0.93–0.99,



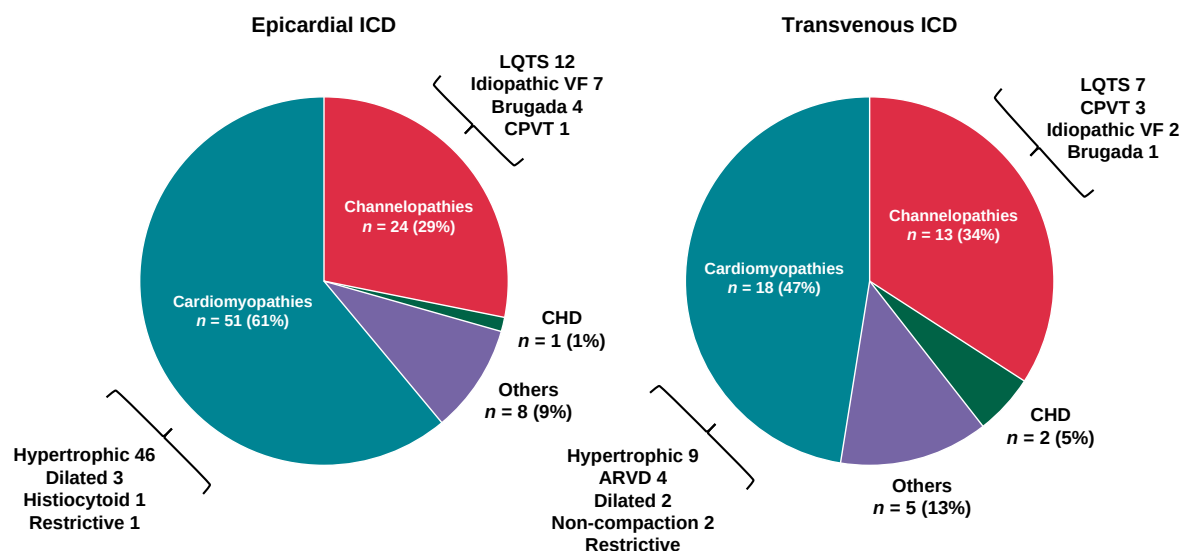
**Figure 2** Age of patients at ICD implantation. ICD, implantable cardioverter defibrillator.

$P=0.042$ ) at ICD implantation were the only factors associated with the risk of ICD lead dysfunction during follow-up. The proportions of patients with ICD lead dysfunction were 36.4, 21.7, and 12.3% in patients aged <6, 6–12, and >12 years, respectively. The proportions of patients with ICD lead dysfunction were 36.4, 25.5, and 5.9% in those weighing <20, 20–40, and >40 kg, respectively. In multivariate analysis, after adjustment of age and weight at implantation, the association between epicardial ICD and the higher risk of ICD lead

dysfunction was no longer significant (HR 5.3, 95% CI 0.7–41.7,  $P=0.112$ ).

### Appropriate implantable cardioverter defibrillator therapies

Overall, 30 (24.6%) patients had at least one appropriate ICD therapy, including 17 (20.2%) with an epicardial ICD and 13 (34.2%) with a



**Figure 3** Underlying heart diseases in patients with epicardial and transvenous ICD. ARVD, arrhythmogenic right ventricular dysplasia; CHD, congenital heart disease; ICD, implantable cardioverter defibrillator; CPVT, catecholaminergic polymorphic ventricular tachycardia; LQTS, long QT syndrome; VF, ventricular fibrillation.

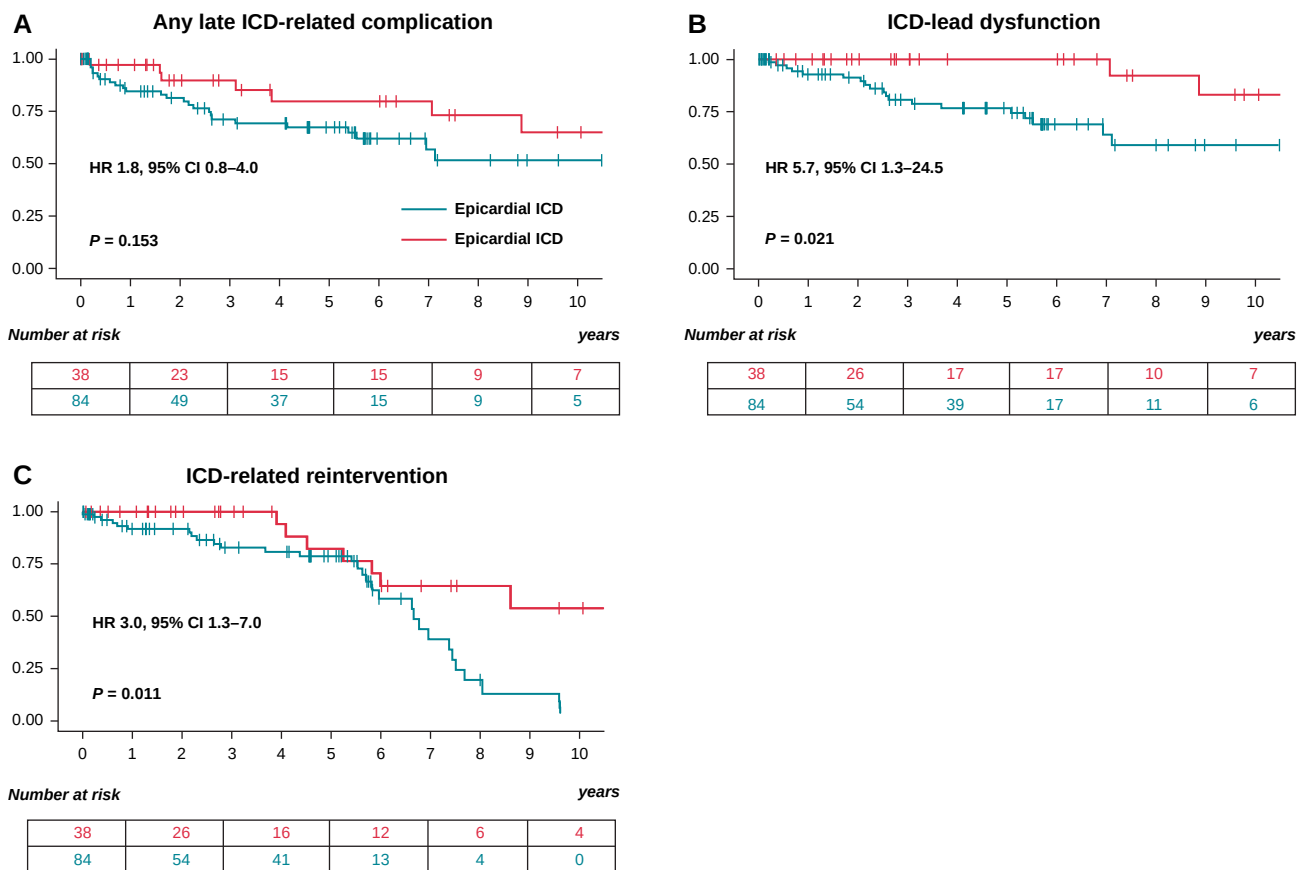
**Table 1** Characteristics of patients at ICD implantation

|                                             | All patients (N = 122) | Transvenous ICD (n = 38) | Epicardial ICD (n = 84) | P-value |
|---------------------------------------------|------------------------|--------------------------|-------------------------|---------|
| Age at implantation (years), mean $\pm$ SD  | 11.5 $\pm$ 3.8         | 13.3 (3.1)               | 10.8 (2.9)              | <0.001  |
| Males, n (%)                                | 70 (57.4)              | 23 (60.5)                | 47 (56.0)               | 0.783   |
| Weight, mean $\pm$ SD (kg)                  | 39.8 $\pm$ 16.1        | 45.5 $\pm$ 13.7          | 37.7 $\pm$ 16.5         | 0.016   |
| Height, mean $\pm$ SD (cm)                  | 145 $\pm$ 22.0         | 154 $\pm$ 17.9           | 142 $\pm$ 22.2          | 0.019   |
| Primary prevention, n (%)                   | 65 (53.3)              | 11 (28.9)                | 54 (64.3)               | 0.001   |
| Type of ICD implanted, n (%)                |                        |                          |                         | <0.001  |
| Single chamber                              | 40 (32.8)              | 28 (73.7)                | 12 (14.3)               | –       |
| Dual chamber                                | 79 (64.8)              | 7 (18.4)                 | 72 (85.7)               | –       |
| Cardiac resynchronization therapy, n (%)    | 3 (2.5)                | 3 (7.9)                  | 0 (0.0)                 | –       |
| Heart disease, n (%)                        |                        |                          |                         | 0.335   |
| Cardiomyopathy                              | 69 (56.6)              | 18 (47.4)                | 51 (60.7)               | –       |
| Channelopathy                               | 37 (30.3)              | 13 (34.2)                | 24 (28.6)               | –       |
| CHD                                         | 3 (2.5)                | 2 (5.3)                  | 1 (1.2)                 | –       |
| Others                                      | 13 (10.7)              | 5 (13.2)                 | 8 (9.5)                 | –       |
| Left ventricular ejection fraction, % (IQR) | 60 (60–65)             | 60 (45–60)               | 60 (60–68)              | 0.001   |

CHD, congenital heart disease; ICD, implantable cardioverter defibrillator; IQR, interquartile range; SD, standard deviation.

transvenous ICD (HR 0.65, 95% CI 0.3–1.4,  $P = 0.262$ ). Considering the main underlying heart diseases, 15 (21.7%) patients with a cardiomyopathy, 10 (27.0%) with a cardiac channelopathies, and 2 (66.7%) with a CHD had at least one appropriate ICD therapy. The respective 5-year incidences of appropriate ICD therapy were 32.7, 26.8, and 33.3% ( $P = 0.8$ ). Only three (2.5%) patients had a ventricular arrhythmia

not successfully treated by their ICD. Among patients with an epicardial ICD, one ventricular arrhythmia was undersensed in one patient and one non-fatal ICD shock failure for VF was reported in another (VF induced during an electrophysiological study). These patients had an ICD system revision. Among patients with a transvenous ICD, one shock failure occurred in one patient with the need for defibrillation vector change.



**Figure 4** Kaplan–Meier curves of survival without any late ICD-related complication (A), ICD lead dysfunction (B), and reintervention (C). CI, confidence interval; HR, hazard ratio; ICD, implantable cardioverter defibrillator.

**Table 2** Late ICD-related complications

| Complications, n (%)          | Transvenous ICD (n = 38) | Epicardial ICD (n = 84) | HR (95% CI)    | P-value |
|-------------------------------|--------------------------|-------------------------|----------------|---------|
| All ICD-related complications | 9 (23.7)                 | 25 (29.8)               | 1.8 (0.8–4.0)  | 0.153   |
| ICD system dysfunction        | 3 (7.9)                  | 19 (22.6)               | 5.7 (1.3–24.5) | 0.021   |
| Any lead dysfunction          | 3 (7.9)                  | 19 (22.6)               | –              | –       |
| Atrial lead dysfunction       | 0 (0.0)                  | 4 (4.8)                 | –              | –       |
| RV lead dysfunction           | 2 (5.3)                  | 5 (6.0)                 | –              | –       |
| Coil dysfunction              | 1 (2.6)                  | 10 (11.9)               | –              | –       |
| Pleural coil                  | –                        | 4/41 (9.8)              | –              | –       |
| Epicardial coil               | –                        | 6/40 (15)               | –              | –       |
| Inappropriate ICD shock       | 3 (7.9)                  | 6 (7.1)                 | 0.9 (0.2–3.8)  | 0.925   |
| ICD infection                 | 2 (5.3)                  | 0 (0.0)                 | –              | –       |
| ICD-related pain              | 1 (2.6)                  | 2 (2.4)                 | 1.0 (0.1–10.9) | 0.991   |
| Pericardial effusion          | 0 (0.0)                  | 1 (1.2)                 | –              | –       |

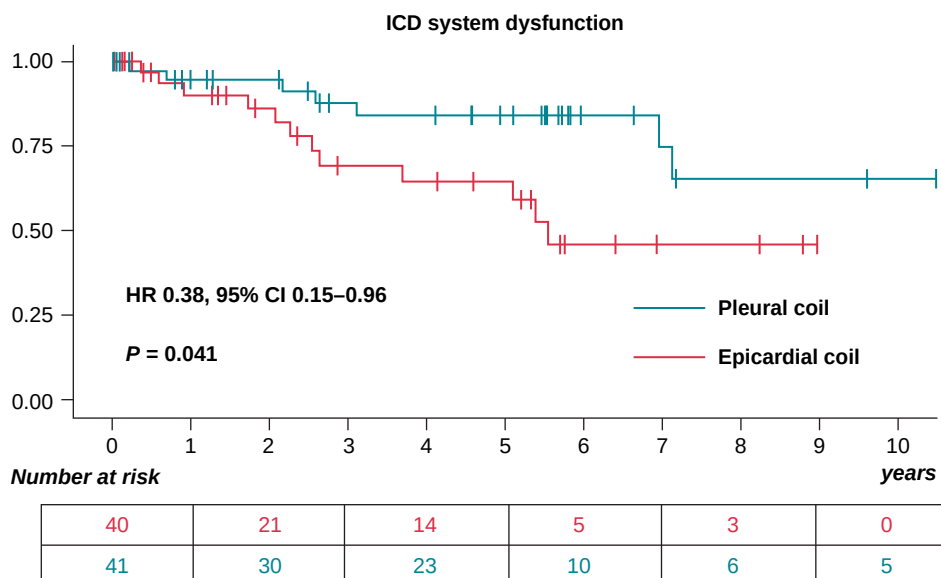
CI, confidence interval; HR, hazard ratio; ICD, implantable cardioverter defibrillator; RV, right ventricle.

## Discussion

In this study, through a large population of children implanted with ICDs, we demonstrate that epicardial ICDs are associated with a

higher burden of early complications and ICD lead dysfunction compared with transvenous ICDs, mainly driven by patient-related characteristics with preferential epicardial implantation in youngest children. The risk of ICD lead failure appears eventually similar





**Figure 5** Kaplan–Meier curves of survival without ICD lead dysfunction in patients with an epicardial ICD. CI, confidence interval; HR, hazard ratio; ICD, implantable cardioverter defibrillator.

in both groups after consideration of age and weight at implantation. Our results also suggest that pleural coils seem to be associated with better outcomes than epicardial coils in this population.

To assess ICDs in children is of particular importance as the use of ICD has significantly increased in paediatric patients in recent years. In the Kid's database, a four-fold increase in the number of ICD implantations was observed from 1997 to 2006, whereas the number of pacemaker implantations remained stable over this same period of time.<sup>18</sup> While ICD was initially mainly used for SCD secondary prevention in first reported experiences,<sup>19</sup> a progressive extension towards primary prevention of SCD underlies this evolution, with approximately half of patients now implanted in a primary prevention setting.<sup>6</sup> Epicardial and transvenous approaches are used, but techniques are centre-dependent and no specific recommendations are provided in international guidelines.<sup>4,5</sup> Hence, it is essential to compare outcomes associated with different techniques in this patient population.

In this cohort, we observed a higher rate of early ICD-related complications in patients with epicardial ICD, particularly in patients with concomitant cardiac surgery (mainly modified Konno surgery). The absence of early complications in those with transvenous ICD was likely favoured by the local preference for the use of epicardial devices for smallest but also for older children, compared with some other expert centres. The burden of overall long-term complications was comparable between epicardial and transvenous ICDs, but the unadjusted incidences of ICD lead dysfunction and ICD-related reintervention were higher with epicardial devices. While different small series reported outcomes associated with epicardial ICDs,<sup>9,10</sup> only a few studies directly compared transvenous and epicardial ICD systems.<sup>6–8</sup> Radbill *et al.* compared 39 patients with epicardial ICD with 78 patients with transvenous ICD and demonstrated that the risk of system failure was higher in the epicardial group (HR 2.9) than in the other group. The proportion of patients with lead failure was also found to be higher among extracardiac ICD systems in another study (29 vs. 7%,  $P=0.001$ ).<sup>7</sup> These studies, however, also included adult patients.

Considering the higher risk of complications reported in children, especially due to growth-related issues, a comparison of those approaches in the most homogeneous population possible appears essential. To our knowledge, we report here the first direct comparison between epicardial and transvenous ICD in a purely paediatric population. Age and weight at implantation were indeed associated with ICD lead dysfunction in our study, and the higher risk of lead failure with epicardial devices was no longer significant after adjustment of these parameters. These findings temper the lower longevity observed with epicardial ICDs and suggest that the higher burden of system dysfunction is primarily driven by patient-related characteristics at implantation. Moreover, although our mean follow-up was almost 5 years, some very long-term complications associated with transvenous ICDs (vascular occlusions, endocarditis...) have also to be considered before implanting this type of device even in older children.

Several other questions remain to be answered. The psychological health of children with ICD is an important issue, and their quality of life has been reported to be lower than healthy controls with more signs of anxiety and depression.<sup>20</sup> This aspect should also be considered when selecting the type of device to be implanted. While the psychological impact of the different ICD systems remains largely unknown, in our experience, epicardial devices are often better accepted by children and parents since the device is less visible under the skin. Furthermore, heterogeneous surgical approaches have been proposed for epicardial coil implantation in different small series, but no comparison of those techniques has been reported.<sup>8–13</sup> Our results, comparing two approaches used in broadly half of patients, suggest that pleural coils may be associated with better outcomes than epicardial coils in this population and should be the preferential option to improve epicardial ICDs' long-term longevity. We can hypothesize that pleural coil positioning is associated with less mechanical strain compared with direct suture on the heart because of repetitive cardiac contractions. Lastly, considering the young age of patients and the lifelong risk of vascular access issues and infection, the S-ICD appears as a promising option to improve the benefit/risk balance in this specific population. However, clinical experience with the use of S-ICD in

paediatric patients is still very limited,<sup>21,22</sup> this approach is generally not suitable in small children under 30 kg,<sup>23</sup> and we still have to learn about the potential impact of growth on long-term appropriate sensing and defibrillation field with this technology.

We acknowledge several limitations. First, this study was observational and retrospective, with inherent biases. Secondly, the study population was enrolled from a single tertiary centre. The extrapolation to other populations or other settings may be questionable; however, paediatric patients with ICD discussion/implantation represent a very specific population managed in referral centres. The monocentric design of the study furthermore allowed us to collect exhaustive data, especially regarding the different surgical approaches used (epicardial vs. pleural coils), and also to compare outcomes associated with the different techniques independently with other parameters that may have impacted the results across different institutions (perioperative management, follow-up settings...). In the absence of specific international guidelines, the preferential approach is highly team-dependent and the high proportion of epicardial devices reflects the local preference for non-transvenous devices for smallest but also for older children (in particular to preserve the venous network), compared with some other expert centres. Thirdly, we had limited information on ICD programming (detection and therapy zones) that was left at the discretion of the treating physician. However, except inappropriate ICD shocks, ICD settings are not associated with ICD-related complications (in particular ICD lead dysfunction), and no differences based on implantation technique are proposed for ICD programming in international expert consensus statements.<sup>24</sup> Fourth, the study inclusion period spans almost two decades with improvement and changes in implant systems and implant technique. However, we did not perform trend analyses given the size of the cohort. Finally, the number of children implanted with an S-ICD was also too modest to analyse outcomes associated with its use in this population compared with transvenous and epicardial ICDs.

## Conclusions

In this large and purely paediatric cohort of children implanted with an ICD, compared with transvenous ICDs, epicardial ICDs were associated with a higher burden of early complications and ICD lead dysfunction, mainly driven by a preferential use in youngest patients. The risk of ICD lead dysfunction was similar in both groups after adjustment of age and weight at implantation. Our findings also demonstrated that pleural coils seemed to be associated with better outcomes than epicardial coils in this population.

## Funding

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**Conflict of interest:** Victor Waldmann is consultant for Abbott, Medtronic, and Withings.

## Data availability

The data underlying this article will be shared on reasonable request to the corresponding author.

## References

- Jordan CP, Freedenberg V, Wang Y, Curtis JP, Gleva MJ, Berul CI. Implant and clinical characteristics for pediatric and congenital heart patients in the national cardiovascular data registry implantable cardioverter defibrillator registry. *Circ Arrhythm Electrophysiol* 2014;**7**:1092–100.
- Baskar S, Bao H, Minges KE, Spar DS, Czosek RJ. Characteristics and outcomes of pediatric patients who undergo placement of implantable cardioverter defibrillators: insights from the National Cardiovascular Data Registry. *Circ Arrhythm Electrophysiol* 2018;**11**:e006542.

- Bogush N, Espinosa RE, Cannon BC, Wackel PL, Okamura H, Friedman PA et al. Selecting the right defibrillator in the younger patient: transvenous, epicardial or subcutaneous? *Int J Cardiol* 2018;**250**:133–8.
- Shah MJ, Silka MJ, Silva JNA, Balaji S, Beach CM, Benjamin MN et al. 2021 PACES expert consensus statement on the indications and management of cardiovascular implantable electronic devices in pediatric patients. *Heart Rhythm* 2021;**18**:1888–924.
- Hernández-Madrid A, Paul T, Abrams D, Aziz PF, Blom NA, Chen J et al. Arrhythmias in congenital heart disease: a position paper of the European Heart Rhythm Association (EHRA), Association for European Paediatric and Congenital Cardiology (AEPC), and the European Society of Cardiology (ESC) working group on grown-up congenital heart disease, endorsed by HRS, PACES, APHRS, and SOLAECE. *Europace* 2018;**20**:1719–1753.
- Berul CI, Van Hare GF, Kertesz NJ, Dubin AM, Cecchin F, Collins KK et al. Results of a multicenter retrospective implantable cardioverter-defibrillator registry of pediatric and congenital heart disease patients. *J Am Coll Cardiol* 2008;**51**:1685–91.
- Krause U, Müller MJ, Wilberg Y, Pletzka M, Backhoff D, Ruschewski W et al. Transvenous and non-transvenous implantable cardioverter-defibrillators in children, adolescents, and adults with congenital heart disease: who is at risk for appropriate and inappropriate shocks? *Europace* 2019;**21**:106–13.
- Radbill AE, Triedman JK, Berul CI, Fynn-Thompson F, Atallah J, Alexander ME et al. System survival of nontransvenous implantable cardioverter-defibrillators compared to transvenous implantable cardioverter-defibrillators in pediatric and congenital heart disease patients. *Heart Rhythm* 2010;**7**:193–8.
- Tomaske M, Prêtre R, Rahn M, Bauersfeld U. Epicardial and pleural lead ICD systems in children and adolescents maintain functionality over 5 years. *Europace* 2008;**10**:1152–6.
- Schneider AE, Burkhart HM, Ackerman MJ, Dearani JA, Wackel P, Cannon BC. Minimally invasive epicardial implantable cardioverter-defibrillator placement for infants and children: an effective alternative to the transvenous approach. *Heart Rhythm* 2016;**13**:1905–12.
- Griksaitis MJ, Rosengarten JA, Gnanapragasam JP, Haw MP, Morgan JM. Implantable cardioverter defibrillator therapy in paediatric practice: a single-centre UK experience with focus on subcutaneous defibrillation. *Europace* 2013;**15**:523–30.
- Winkler F, Dave H, Weber R, Gass M, Balmer C. Long-term outcome of epicardial implantable cardioverter-defibrillator systems in children: results justify its preference in paediatric patients. *Europace* 2018;**20**:1484–90.
- Müller MJ, Dieks JK, Backhoff D, Schneider HE, Ruschewski W, Tirilomis T et al. Efficacy and safety of non-transvenous cardioverter defibrillators in infants and young children. *J Interv Card Electrophysiol* 2019;**54**:151–9.
- Harris PA, Taylor R, Thielke R, Payne J, Gonzalez N, Conde JG. Research electronic data capture (REDCap)—a metadata-driven methodology and workflow process for providing translational research informatics support. *J Biomed Inform* 2009;**42**:377–81.
- Stout KK, Daniels CJ, Aboulhosn JA, Bozkurt B, Broberg CS, Colman JM et al. 2018 AHA/ACC guideline for the management of adults with congenital heart disease: a report of the American College of Cardiology/American Heart Association task force on clinical practice guidelines. *J Am Coll Cardiol* 2019;**73**:e81–e192.
- Baumgartner H, De Backer J, Babu-Narayan SV, Budts W, Chessa M, Diller G-P et al. 2020 ESC guidelines for the management of adult congenital heart disease: the task force for the management of adult congenital heart disease of the European Society of Cardiology (ESC). *Eur Heart J* 2021;**42**:563–645.
- von Elm E, Altman DG, Egger M, Pocock SJ, Gøtzsche PC, Vandenbroucke JP et al. Strengthening the reporting of observational studies in epidemiology (STROBE) statement: guidelines for reporting observational studies. *BMJ* 2007;**335**:806–8.
- Czosek RJ, Meganathan K, Anderson JB, Knilians TK, Marino BS, Heaton PC. Cardiac rhythm devices in the pediatric population: utilization and complications. *Heart Rhythm* 2012;**9**:199–208.
- Silka MJ, Kron J, Dunnigan A, Dick M. Sudden cardiac death and the use of implantable cardioverter-defibrillators in pediatric patients. The Pediatric Electrophysiology Society. *Circulation* 1993;**87**:800–7.
- Pyngottu A, Werner H, Lehmann P, Balmer C. Health-related quality of life and psychological adjustment of children and adolescents with pacemakers and implantable cardioverter defibrillators: a systematic review. *Pediatr Cardiol* 2019;**40**:1–16.
- Silvetti MS, Pazzano V, Verticelli L, Battipaglia I, Saputo FA, Albanese S et al. Subcutaneous implantable cardioverter-defibrillator: is it ready for use in children and young adults? A single-centre study. *Europace* 2018;**20**:1966–73.
- Sato A, Hasegawa Y, Haniu H, Shiraishi S, Yagihara N, Iijima K et al. Replacement of an implantable cardioverter-defibrillator (ICD) with a new standard subcutaneous ICD system in a patient with Jervell and Lange-Nielsen syndrome. *Int Heart J* 2019;**60**:1206–10.
- Reeves JG, Kim JS, Mitchell MB, McCanta AC. Implantation of the subcutaneous implantable cardioverter-defibrillator with retroperitoneal generator placement in a child with hypoplastic left heart syndrome. *HeartRhythm Case Rep* 2015;**1**:176–9.
- Stiles MK, Fauchier L, Morillo CA, Wilkoff BL. 2019 HRS/EHRA/APHRS/LAHS focused update to 2015 expert consensus statement on optimal implantable cardioverter-defibrillator programming and testing. *Heart Rhythm* 2020;**17**:e220–8.