Epicardial and pleural lead ICD systems in children and adolescents maintain functionality over 5 years

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Aims The optimal implantable cardioverter defibrillator (ICD) system implant technique has not yet been defined in young patients and those with congenital heart disease (CHD). We describe our 5-year experience with epicardial pacing/sensing leads secured on the left cardiac chambers and a pleural defibrillation lead insertion along the third intercostal space.

Methods and results Implantable cardioverter defibrillator systems were implanted in 15 children and adolescents (age: 2.9 –20.0 years) for primary (n = 11) or secondary (n = 4) prevention. Underlying CHD were hypertrophic (n = 10) or dilative cardiomyopathies (n = 2), primary electrical diseases (n = 2), and transposition of the great arteries (n = 1). Devices were placed in the rectus sheath (n = 5), or within the diaphragm (n = 10). Median defibrillation threshold at implant was 15 J (range: 10 –25). During 5 years of follow-up (median: 22 months), nine appropriate and two inappropriate ICD discharges occurred. Four system revisions were required due to device recall, pleural lead dislodgement, epicardial lead fracture, and insulation break. Twelve months after the implantation, defibrillation threshold testing demonstrated stable thresholds of ≤20 J in five patients.

Conclusion Our 5-year experience demonstrates the efficacy of epicardial and pleural lead ICD systems. Inappropriate shocks and lead failures are observed as in other ICD systems. It represents an alternative implant technique for young and active patients and those without venous access.

KEYWORDS
Implantable cardioverter defibrillator; Congenital heart disease; Implantation technique; Paediatric

Introduction

Implantable cardioverter defibrillators (ICDs) in adults and young patients have proven to be an effective therapy for life-threatening ventricular arrhythmias. Thus, they are increasingly used for the primary and secondary prevention of sudden cardiac death.1–3 However, small vessel size or cardiovascular abnormalities may preclude transvenous leads in young patients and adults with congenital heart disease (CHD).

The optimal ICD system implant technique in the presence of limited venous access to the heart has not yet been defined.4–7 Growth and high physical activity levels with possible physical impact are risk factors for complications in the paediatric population.8,9

The authors previously published their initial experience describing a new implant technique of an ICD system with abdominal or infracardiac horizontal device position, epicardial pacing and sensing leads, and a pleural defibrillation lead placement in patients.6

The purpose of this study was to evaluate the performance of this ICD system implant technique with the inclusion of more patients and a prolonged follow-up.

Patients and methods

Study patients
A total of 15 children and adolescents were prospectively enrolled. Baseline characteristics and indications for ICD therapy are depicted in Table 1. Beta-blocker therapy was received by 13 of the 15 (86%) patients. The study protocol was performed with Institutional Ethics Committee approval, and parental written informed consent was obtained.

Implantable cardioverter defibrillator system implantation
As previously described in detail,6 the surgical access for lead implantation was a muscle sparing left lateral thoracotomy in the forth intercostal space or sternotomy in the case of concomitant cardiac surgery. The defibrillation lead (Medtronic 6937, Medtronic, Inc., Minneapolis, MN, USA) was inserted in a tunnel created along the third intercostal space. Bipolar steroid-eluting epicardial leads

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Table 1 Baseline characteristics at implantable cardioverter defibrillator system implant in 15 patients

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>Study group</th>
</tr>
</thead>
<tbody>
<tr>
<td>Male/female (n)</td>
<td>11/ 4</td>
</tr>
<tr>
<td>Age at implantation (years)</td>
<td>12.5 (2.9–20.0)</td>
</tr>
<tr>
<td>Weight at implantation (kg)</td>
<td>36.5 (13.5–95.0)</td>
</tr>
<tr>
<td>Follow-up (months)</td>
<td>22 (2–60)</td>
</tr>
<tr>
<td>Underlying congenital heart disease (n)</td>
<td>10</td>
</tr>
<tr>
<td>HCM</td>
<td>2</td>
</tr>
<tr>
<td>Dilative cardiomyopathy</td>
<td>1</td>
</tr>
<tr>
<td>D-TGA, with congestive heart failure</td>
<td>1</td>
</tr>
<tr>
<td>Catecholaminergic VT</td>
<td>1</td>
</tr>
<tr>
<td>Brugada syndrome</td>
<td>1</td>
</tr>
<tr>
<td>Primary prevention (n)</td>
<td></td>
</tr>
<tr>
<td>Family history with sudden death</td>
<td>6</td>
</tr>
<tr>
<td>HCM with obstruction and excessive hypertrophy</td>
<td>5</td>
</tr>
<tr>
<td>Secondary prevention (n)</td>
<td></td>
</tr>
<tr>
<td>Cardiac syncope</td>
<td>1</td>
</tr>
<tr>
<td>Cardiopulmonary resuscitation</td>
<td>3</td>
</tr>
<tr>
<td>ICD system implant technique (n)</td>
<td></td>
</tr>
<tr>
<td>Left lateral thoracotomy</td>
<td>9</td>
</tr>
<tr>
<td>Sternotomy with concomitant cardiac surgery</td>
<td>6</td>
</tr>
</tbody>
</table>

D-TGA, D-transposition of the great arteries; HCM, hypertrophic cardiomyopathy; ICD, implantable cardioverter defibrillator.

Data are given as medians (range).

Data acquisition

Defibrillation thresholds, lead impedances, and sensing and pacing thresholds were measured at the time of implantation. In patients with concomitant cardiac surgery, defibrillation thresholds of 20 J were accepted, and no further testing was carried out at lower energy settings. ICD and clinical follow-up data were obtained at implant, 1 month, and semi-annual intervals thereafter. Defibrillation threshold retesting was scheduled every 12 months after the ICD system implant, provided that ventricular fibrillation was inducible at implant. Chest radiographs were acquired 1 day after ICD implantation and scheduled 12 monthly thereafter for the documentation of stable lead and device positions.

Statistical analysis

Data are expressed as either median (range) or mean (± standard deviation) depending on the distribution pattern of the data evaluated by the Kolmogorov–Smirnov test. Descriptive statistics were applied if appropriate. Wilcoxon signed rank tests were used to compare telemetry data at various follow-up. A P-value less than 0.05 was considered statistically significant.

Results

Implantable cardioverter defibrillator system implantation

No implant complications were observed. Adequate defibrillation thresholds were obtained in 12 patients; in 3 patients with hypertrophic cardiomyopathy, ventricular fibrillation was not inducible. The median lowest tested defibrillation threshold at implant was 15 J (range: 10–25), even when testing was performed immediately after cardiopulmonary bypass surgery (n = 6). A second mediastinal defibrillation lead was used to achieve a defibrillation threshold of 20 J in patients with hypertrophic obstructive cardiomyopathy. Cardiopulmonary bypass surgery for the resection of a subaortic stenosis may have altered defibrillation threshold in this patient.

Telemetry data at various follow-up

Detailed lead performance is depicted in Table 2. Impedances of the pleural defibrillator lead did not change significantly during follow-up. Impedances of the atrial and ventricular epicardial leads were high at implantation and decreased significantly until first follow-up after 1 month. No changes were noted during further follow-up. Likewise, sensing and pacing thresholds of the atrial and ventricular epicardial leads remained constant over time. In nine patients, atrial pacing was required, with predominant (>80%) atrial pacing in two patients. Dual chamber pacing was required in two patients, including biventricular pacing in one patient suffering from complete atrioventricular block and congestive heart failure. All other patients were in sinus rhythm.

Defibrillation thresholds

The lowest tested defibrillation thresholds were stable in five patients retested after 12 month [implant: 20 J (15–25) vs. 12 months: 17.5 J (15–20); P = 0.34]. Moreover, two patients were retested at 24 months, and one at 48 months after the ICD system implant. Measurements indicated no change in the previous lowest tested defibrillation thresholds.

Implantable cardioverter defibrillator discharges

During a maximum follow-up of 60 months, nine appropriate ICD discharges leading to the successful termination of ventricular tachycardia were seen in four patients. Charging was aborted twice after spontaneous ventricular tachycardia termination in one patient. Two inappropriate shocks were documented due to sinus tachycardia and T-wave oversensing in two patients.

System revisions

System revisions were required in four patients. Dislodgement of a pleural defibrillation lead in the early learning curve was detected by chest radiography. One ventricular lead insulation break was observed 17 months post-implant. Moreover, after a growth spurt of 20 cm at 31 months post-implant, an atrial and ventricular lead fracture was detected (Figure 1) in an 11-year old girl. All above-mentioned system revisions occurred for devices positioned...
Discussion

As in adults, the use of ICD in the paediatric population has proven to be effective in the therapy of life-threatening ventricular arrhythmias. The optimum positioning of the defibrillation electrode in small patients or those with limited venous access as seen in CHD is still controversial. The main findings with the new ICD system implant technique were adequate defibrillation thresholds achieved when tested immediately after cardiopulmonary bypass surgery. In all patients retested, lowest tested defibrillation thresholds were stable at or below 20 J. Moreover, sensing and pacing thresholds of the epicardial atrial and ventricular leads remained stable over time.

A main risk for complications in children is related to lead failure with a high incidence of fracture or dislodgement of the defibrillation lead, likely due to physical activity, growth-related distortion, and unfavourable position in the rectus muscle sheath. In our patient cohort, limited venous access as seen in CHD is still controversial. 

Figure 1. Lead fracture. Radiographically visible fracture of the atrial and ventricular leads requiring system revision at 31 months after implantation.

Table 2 Measured data from implantable cardioverter defibrillator and pacemaker telemetry: at implant and follow-up

<table>
<thead>
<tr>
<th></th>
<th>Implant</th>
<th>1 month</th>
<th>6 months</th>
<th>12 months</th>
<th>18 months</th>
<th>24 months</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patients tested</td>
<td>15/15</td>
<td>15/15</td>
<td>13/15</td>
<td>9/15</td>
<td>8/15</td>
<td>8/15</td>
</tr>
<tr>
<td>Atrial lead</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>A wave (mV)</td>
<td>5.7 ± 2.6</td>
<td>4.7 ± 2.4</td>
<td>5.4 ± 2.2</td>
<td>4.3 ± 1.3</td>
<td>4.0 ± 1.3</td>
<td>4.2 ± 0.8</td>
</tr>
<tr>
<td>Pacing threshold (V)a</td>
<td>0.5 ± 0.4</td>
<td>0.5 ± 0.2</td>
<td>0.7 ± 0.3</td>
<td>0.6 ± 0.0</td>
<td>0.7 ± 0.1</td>
<td>0.6 ± 0.1</td>
</tr>
<tr>
<td>Impedance (Ω)</td>
<td>932 ± 189</td>
<td>653 ± 79</td>
<td>646 ± 176</td>
<td>597 ± 64</td>
<td>604 ± 50</td>
<td>595 ± 88</td>
</tr>
<tr>
<td>Ventricular lead</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>R wave (mV)</td>
<td>14.8 ± 6.5</td>
<td>14.3 ± 6.5</td>
<td>15.4 ± 5.9</td>
<td>13.6 ± 6.1</td>
<td>14.6 ± 7.4</td>
<td>13.7 ± 7.6</td>
</tr>
<tr>
<td>Pacing threshold (V)a</td>
<td>1.2 ± 0.5</td>
<td>1.1 ± 0.4</td>
<td>1.4 ± 0.8</td>
<td>1.4 ± 0.8</td>
<td>1.5 ± 1.1</td>
<td>1.6 ± 1.1</td>
</tr>
<tr>
<td>Impedance (Ω)</td>
<td>1216 ± 371</td>
<td>641 ± 108</td>
<td>612 ± 129</td>
<td>612 ± 166</td>
<td>594 ± 163</td>
<td>661 ± 126</td>
</tr>
<tr>
<td>Pleural defibrillation lead</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Impedance (Ω)</td>
<td>66 ± 16</td>
<td>67 ± 11</td>
<td>75 ± 10</td>
<td>76 ± 9</td>
<td>73 ± 19</td>
<td>69 ± 12</td>
</tr>
</tbody>
</table>

Data are given as means ± SD.
aCalculated for 0.5 ms pulse duration.
bP < 0.05 (significant decrease of measured data during follow-up).
As described previously, a main difficulty encountered in the paediatric population with CHD is high defibrillation threshold at ICD system implant. To optimize the electrical field, the device was placed in the horizontal position underneath the heart within the diaphragm. Of importance, for six patients in our study cohort with concomitant cardiac surgery, true defibrillation thresholds were not obtained. The lowest energy tested in those was 20 J and was used as a surrogate for true defibrillation thresholds. However, the maximum lowest tested defibrillation threshold was 25 J. Regular defibrillation threshold testing has been proposed during follow-up in the growing patient and those with CHD. Of importance, defibrillation threshold testing in our patient cohort remained stable during follow-up with the maximum lowest tested defibrillation threshold of 20 J.

Previous studies have reported on non-standard implantation techniques with pericardial coils or subcutaneous/epicardial defibrillation leads. Two of the studies offer a similar median follow-up to our study. The incidence of inappropriate shocks was higher with pericardial coils [3/8 (38%) patients] and subcutaneous/epicardial leads [4/22 (18%) patients] when compared with our study cohort [2/15 (13%) patients]. Lead failure or migration requiring system revision was comparable between pericardial coils [1/8 (13%) patients], subcutaneous/epicardial leads [4/22 (18%) patients], and our implant technique [3/15 (20%) patients]. However, the small number of patients in all three mentioned studies limits any statistically valid determination of a conclusive statement. With the improved implant technique by means of devices in the infracardiac horizontal position, no lead failures were observed during follow-up. Theoretically, a subpleural insertion provides limited lead stress through cardiac contraction or respiratory movements.

An intra-thoracic, horizontal position of the device underneath the heart limits lead tension, compared with placement in the rectus muscle sheath. The intrathoracic lead and device insertion ensure a safe ICD system position in active patients in the case of physical impact and provide an excellent functional status in terms of arm movements for profession and sports. Moreover, the muscle sparing mini-left axillary approach for left ventricular epicardial lead insertion used in our institution has been associated with a low complication rate, excellent cosmetic results, and stable sensing and pacing thresholds.

However, there are also some potential disadvantages of an infracardiac device placed within the diaphragm. If a device has to be replaced, careful dissection from its pocket closely related to the right ventricle has to be accomplished. So far, infracardiac devices did not have to be replaced in our cohort. No complications, such as pressure on the vena cava inferior, pocket infection, or device migration were observed. Chest radiographs scheduled every 12 months demonstrated stable position of the device.

Clinical implications

With the evolving indications for ICD therapy, there are major advantages of the presented implant technique. Epicardial leads may be ideal for pacing and sensing functions of the ICD system. A superior performance of ventricular sensing was demonstrated for left ventricular epicardial leads. Moreover, the placement of left ventricular leads facilitates left ventricular pacing in patients with a diseased right ventricle as well as biventricular or single-site left ventricular pacing if additional resynchronization therapy is required (Figure 2). The majority of patients with structural CHD and limited venous access in the need for an ICD therapy are those suffering from chronic pressure or volume overload of the ventricle due to TOF, D-transposition of the great arteries following Mustard and Senning repair, and left ventricular outflow tract obstructions. The risk of sudden death appears to be age-dependent, thereby the need for ICD therapy is primarily increasing in young adults. However, an increasing number of patients with univentricular heart is palliated and may suffer from advanced systemic ventricular function. Implantable cardioverter defibrillator therapy potentially evolves in those children and.....
adolescents with limited venous access and necessitates epicardial lead implantation. Likewise, the intention to preserve the venous access often precludes a transvenous approach and requires epicardial lead implantation.

**Study limitation**

Limitations of the study include the restricted follow-up period, revealing nine effectively terminated malignant arrhythmias in four patients. However, ICD systems were implanted for the primary prevention of sudden death in the majority of our study cohort. Thus, a higher incidence of malignant tachycardia and successful ICD discharges cannot easily be anticipated even in a prolonged follow-up. System revisions were necessary in four patients including one device recall, and one defibrillation lead dislodgement, early in the learning period. As lead dislodgement may have been facilitated by tension from the abdominal (rectus muscle sheath) ICD position, the refined technique with infracardiac horizontal placement of the device was performed at revision.

**Conclusion**

In conclusion, the implantation of ICD systems with epicardial sensing and pacing leads, and a pleural placement of the defibrillation lead, is feasible and safe in children and adolescents with CHD. An infracardiac horizontal position of the device optimizes the electrical field and results in a safe and protected position. An epicardial and pleural lead ICD system may be an alternative ICD implant technique for young patients and those with CHD without transvenous access.

**Conflict of interest:** none declared.

**References**


