Subcutaneous implantable cardioverter-defibrillator and the two-incision intermuscular technique in pediatric patients — a single center experience

Authors: Maciej Jan Pitak, Marek Jastrzębski, Anna Rudek-Budzyńska, Piotr Weryński, Joachim Winter, Sebastian Góreczny

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**Short title:** S-ICD and the intermuscular technique in children — a single center experience

**Conflict of interest:** None declared.

**Correspondence to:**
Maciej Jan Pitak MD, PhD,
Department of Pediatric Cardiology, University Children’s Hospital, Jagiellonian University Medical College, Wielicka 265, 30–663 Kraków, Poland,
phone +48 12 333 90 50,
e-mail: mpitak@gmail.com

**INTRODUCTION**
For the past decade the subcutaneous implantable cardioverter-defibrillator (S-ICD) has provided a safe and effective option to prevent sudden cardiac death for selected patients [1, 2]. This alternative to transvenous implantable cardioverter-defibrillator (TV-ICD) is superior for patients with difficult vascular access, high risk of infection and expected lead failure in patients with anticipated life-long therapy [3, 4]. However, it is not appropriate for patients who need bradycardia-, antitachycardia- or resynchronization pacing [3–5]. With these limitations the S-ICD has shown itself to be non-inferior to TV-ICD in several studies in adults [1–3]. There are few publications regarding S-ICD implantation in pediatric patients, probably due to smaller subject population [3, 4, 6]. Investigators emphasize importance of safety offered by S-ICD
comparing with TV-ICD in adolescent patients [7]. We report our initial experience with 8 children referred for S-ICD implantation to our institution.

**METHODS**

Patients were considered for ICD implantation according to the current guidelines.[5, 8] Preimplant screening is routinely required to ensure appropriate sensing and to reduce the risk of inappropriate shocks. The aim of this procedure is to assess the accuracy of QRS discrimination at least in 1 of the 3 sensing vectors. Screening was performed in supine and standing position using an automatic screening tool (Boston Scientific™ ZOOM programmer). In addition to the standard protocol, we tested all patients lying on the left and on the right side. In case of inappropriate screening results with the standard device and electrode positions, we changed the lead position from the left sternum border to the right, and/or the can more posteriorly and repeated screening. We believe screening pass with not one positive sensing vector as recommended by hardware producer, but 2 is justified by specificity of children population. Because of faster heart rate and higher motoric activity, we may observe more difficult and variable sensing conditions. Testing with electrode positioned also on the right sternum border is reasonable considering child chest anatomy: child’s heart is proportionally bigger in chest. This should provide with better sensing and effective shock vectors.

In 7 patients who passed screening, a S-ICD was implanted. Prior to the procedure in the operation room, screening was again confirmed using fluoroscopy. Final lead and can position, and skin incisions were marked. All implantations were performed by one operator (MJ).

Under general anesthesia the device (BostonScientific Emblem™ A219) was implanted intermuscularly between the anterior surface of serratus anterior and the posterior surface of latissimus dorsi [9]. To avoid a third superior parasternal incision the lead (model 3501) was subcutaneously tunneled from a subxiphoid incision parallel to the sternum using an 11F delivery system. At the end of the procedure VF was induced by a 50 Hz burst and terminated in all patients with the first 65 J standard polarity shock. All children had individually programmed two-zone shock set up: conditional shock zone 200–210 bpm and shock zone 240 bpm SMART PASS filter on. The patients were seen in the outpatient clinic 1 and after that every 6 months. The study was approved by the local ethics committee according to the Declaration of Helsinki.

Distribution of patients’ characteristic was done by presenting of data range and median values for quantitative data and number count for qualitative data. Microsoft Excel© version 16.50 was used for calculations.
RESULTS AND DISCUSSION

Between January 2018 and February 2021, 8 children met ICD implantation criteria. Patients' data are presented in Table 1. Seven patients passed screening in two vectors and a S-ICD system was implanted. In patient JT with Danon syndrome, hypertrophic cardiomyopathy (HCMP) and preexcitation syndrome, initial screening failed. We performed radiofrequency ablation of the accessory pathway. Despite narrowing of QRS, this patient failed the screening again.

Patients’ age at implantation was between 9–17 years (median 12.5); body weight 32–60 kg (median 44.5); body height 134–173 cm (median 159); BMI 15.60–20.02 kg/m² (median 19.33). Follow-up ranged from 3 to 40 months (median 14).

Through implantation procedure no technical problems occurred. Regardless of patients’ anatomy even in the youngest patient, all were successfully implanted using the 2-incision intermuscular technique. Sensing vectors remained stable in all children during follow-up.

We chose standard lead and device can position in 3 patients, whereas 4 children with HCMP had appropriate sensing only in a modified lead and can position. Here we implanted the lead right parasternal and the can posterior to the mid-axillary line.

Any pocket complication, erosion of the lead tip or incisional infection occurred. With good cosmetic effect, even in the youngest patients, the device didn’t cause any discomfort or mobility restriction.

At follow-up neither appropriate nor inappropriate shocks were observed in any patient. Sensing vectors remained stable in all patients and no T wave oversensing occurred.

Implantable cardioverter-defibrillator in sudden cardiac death prevention remains to be a challenging therapy in young patients with long life expectancy. Lead failure are main issues for both transvenous and epicardial lead systems [9]. The highest complication rates were observed in pediatric patients [10, 11]. As observational studies show, risk of lead failure in 5-year follow-up reaches 40% in TV-ICD [13]. Venous obstruction, system infections and thromboembolism, high risk lead extraction are frequent complications. Comparing various cohorts of patients, complication rates didn’t differ significantly and remained comparable [13]. The answer to such issues may be the S-ICD. The S-ICD eliminates the need for endovascular or epicardial placement of leads. The well-known problems of transvenous leads are avoided.

Subcutaneous lead longevity needs further investigations, but current data are encouraging [1, 2].
The S-ICD system is limited by the lack of bradycardia, antitachycardia and resynchronization pacing, being a simple shock box. Careful preoperative selection of the patients is therefore mandatory.

Accurate QRS sensing remains challenging in S-ICD systems. Inappropriate shocks are most frequent complications in subcutaneous systems [14]. In our cohort we were able to show that these concerns can be overcome by proper patient selection, extended screening and careful implantation technique. We believe that we didn’t observe any inappropriate shock due to our rigorous screening and device implantation under fluoroscopy. We encountered preoperatively difficulties in obtaining proper sensing vectors in patients with HCMP, probably due to oversensed high-voltage T, wide and fragmented QRS. The solution was right parasternal lead position and dorsal device position behind the mid-axillary line [15].

Another point is large device size: Emblem™ A219: volume 59.5 ml, and size 83.1 × 69.1 × 12.7 mm. With the intermuscular two-incision technique we obtained excellent functional and cosmetic result. There was no restriction in arm and shoulder mobility. We preferred the 2-incision technique to the 3-incision technique to avoid lead tip erosion and subsequent local infections. The 2-incision technique minimize the risk associated with traditional three-incision technique especially with children [6].

This technique enables S-ICD implantation in children under 10 years of age. Current outcomes are promising in terms of lack of lead and pocket-related complications and excellent sensing accuracy.

REFERENCES


### Table 1. Patients characteristics

<table>
<thead>
<tr>
<th>Patient number</th>
<th>Age at implantation, years/sex</th>
<th>Body weight, kg</th>
<th>Body height, cm</th>
<th>BMI kg/m²</th>
<th>Diagnosis</th>
<th>Indication</th>
<th>Screenig result/Sensing vector used</th>
<th>Shock zone (conditional) obligatory</th>
<th>Lead position</th>
<th>Follow-up, months</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>13/F</td>
<td>44</td>
<td>158</td>
<td>17.86</td>
<td>Anders-Tawil S.</td>
<td>Secondary prevention</td>
<td>Positive/Alternate</td>
<td>(210) 240</td>
<td>Left parasternal</td>
<td>40</td>
</tr>
<tr>
<td>2</td>
<td>9/M</td>
<td>39</td>
<td>136</td>
<td>21.08</td>
<td>HOCM</td>
<td>Primary prevention</td>
<td>Positive/Primary</td>
<td>(210) 240</td>
<td>Right parasternal</td>
<td>17</td>
</tr>
<tr>
<td>3</td>
<td>17/F</td>
<td>59</td>
<td>165</td>
<td>21.67</td>
<td>Idiopathic VF</td>
<td>Secondary prevention</td>
<td>Positive/Primary</td>
<td>(210) 240</td>
<td>Left parasternal</td>
<td>17</td>
</tr>
<tr>
<td>4</td>
<td>9/M</td>
<td>32</td>
<td>134</td>
<td>17.68</td>
<td>HNOCMP</td>
<td>Primary prevention</td>
<td>Positive/Primary</td>
<td>(210) 240</td>
<td>Right parasternal</td>
<td>14</td>
</tr>
<tr>
<td>5</td>
<td>12/M</td>
<td>49</td>
<td>163</td>
<td>18.63</td>
<td>HOCMP</td>
<td>Primary prevention</td>
<td>Positive/Primary</td>
<td>(210) 240</td>
<td>Right parasternal</td>
<td>14</td>
</tr>
<tr>
<td>6</td>
<td>17/F</td>
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<td>Secondary prevention</td>
<td>Positive/Secondary</td>
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<td>Right parasternal</td>
<td>14</td>
</tr>
<tr>
<td>7</td>
<td>9/M</td>
<td>45</td>
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<td>20.50</td>
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<td>(210) 240</td>
<td>—</td>
<td>—</td>
</tr>
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<td>14/F</td>
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<td>Positive/Primary</td>
<td>(210) 240</td>
<td>Left parasternal</td>
<td>3</td>
</tr>
</tbody>
</table>

Abbreviations: HNOCM, hypertrophic non-obstructive cardiomyopathy; HOCMP, hypertrophic obstructive cardiomyopathy; LV, left ventricle; VF, ventricular fibrillation