

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

Maciej Jan Pitak¹, Marek Jastrzębski², Anna Rudek-Budzyńska¹, Piotr Weryński¹, Joachim Winter³, Sebastian Górcznyi¹

¹Department of Pediatric Cardiology, University Children's Hospital, Jagiellonian University Medical College, Kraków, Poland

²^{1st} Department of Cardiology, Interventional Electrocardiology and Hypertension, Jagiellonian University Medical College, Kraków, Poland

³Department of Cardiology and Rhythmology, Augusta Hospital, Duesseldorf, Germany

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

Copyright by the Author(s),
2021

Kardiologia Polska. 2021;
79 (9): 1025–1027;
DOI: 10.33963/KPa2021.0081

Received:

June 21, 2021

Revision accepted:

August 4, 2021

Published online:

August 4, 2021

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 a smaller subject population [3, 4, 6]. Investigators emphasize the 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]. Pre-implant 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. The screening was performed in a supine and standing position using an automatic screening tool (Boston Scientific™ ZOOM programmer, Marlborough, MA, USA). In addition to the standard protocol, we tested all patients lying on the

left and 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 the producer of the hardware, but with 2 is justified by the specificity of the children population. Because of faster heart rate and higher motoric activity, we may observe more difficult and variable sensing conditions. Testing with an electrode positioned also on the right sternum border is reasonable considering child chest anatomy: child's heart is proportionally bigger in the chest. This should provide better sensing and effective shock vectors.

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

Under general anesthesia, the device (Boston Scientific Emblem™ A219, Marlborough, MA, USA) 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 tunneled subcutaneously 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

Table 1. Patient characteristics

Patient number	Age at implantation, years /sex	Body weight, kg	Body height, cm	BMI, kg/m ²	Diagnosis	Indication	Screening result/Sensing vector used	Shock zone (conditional) obligatory	Lead position	Follow-up, months
1	13/F	44	158	17.86	Andersen-Tawil S.	Secondary prevention	Positive/Alternate	(210) 240	Left parasternal	40
2	9/M	39	136	21.08	HOCM	Primary prevention	Positive/Primary	(210) 240	Right parasternal	17
3	17/F	59	165	21.67	Idiopathic VF	Secondary prevention	Positive/Primary	(210) 240	Left parasternal	17
4	9/M	32	134	17.68	HNOCMP	Primary prevention	Positive/Primary	(210) 240	Right parasternal	14
5	12/M	49	163	18.63	HOCMP	Primary prevention	Positive/Primary	(210) 240	Right parasternal	14
6	17/F	60	173	20.04	HOCMP	Secondary prevention	Positive/Secondary	(200) 240	Right parasternal	14
7	9/M	45	148	20.50	Danon S.	Primary prevention	No vector available	(210) 240	—	—
8	14/F	40	160	15.60	LV tumor	Secondary prevention	Positive/Primary	(210) 240	Left parasternal	3

Abbreviations: BMI, body mass index; HNOCMP, hypertrophic non-obstructive cardiomyopathy; HOCMP, hypertrophic obstructive cardiomyopathy; LV, left ventricle; VF, ventricular fibrillation

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 month after the procedure and after that every 6 months. The study was approved by the local ethics committee according to the Declaration of Helsinki.

The distribution of patient characteristics was done by presenting data ranges 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 an S-ICD system was implanted. In patient no. 7 with Danon syndrome, hypertrophic cardiomyopathy (HCMP), and pre-excitation 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 and 17 years (median, 12.5); body weight between 32 and 60 kg (median, 44.5); body height between 134 and 173 cm (median, 159); body mass index (BMI) 15.60–20.02 kg/m² (median, 19.33). Follow-up ranged from 3 to 40 months (median, 14).

Throughout the 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.

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. In the latter cases, 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 did not 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 a challenging therapy in young patients with long life expectancy. Lead failure is the main issue for both transvenous and epicardial lead systems [9]. The highest complication rates were observed in pediatric patients [10, 11]. As observational studies show, the risk of lead failure in a 5-year follow-up reaches 40% in TV-ICD [12]. Venous obstruction, system infections and thromboembolism, high-risk lead extraction are frequent complications. When various cohorts of patients were compared, complication rates did not differ significantly and remained comparable [13].

The answer to such issues may be the S-ICD. The S-ICD eliminates the need for the 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 the 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 techniques. We believe that we did not 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 the right parasternal lead position and dorsal device position behind the mid-axillary line [15].

Another point is a 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 results. 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 minimizes the risk associated with the traditional 3-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.

Article information

Conflict of interest: None declared.

Open access: This article is available in open access under Creative Commons Attribution-Non-Commercial-No Derivatives 4.0 International (CC BY-NC-ND 4.0) license, allowing to download articles and share them with others as long as they credit the authors and the publisher, but without permission to change them in any way or use them commercially. For commercial use, please contact the journal office at kardiologiapolska@ptkardio.pl.

How to cite: Pitak MJ, Jastrzębski M, Rudek-Budzyńska A, et al. S-ICD and the intermuscular technique in children — a single center experience. *Kardiol Pol.* 2021; 79(9): 1025–1027, doi: 10.33963/KPa2021.0081.

REFERENCES

- Knops R, Nordkamp LO, Delnoy PP, et al. Subcutaneous or transvenous defibrillator therapy. *N Engl J Med.* 2020; 383(6): 526–536, doi: 10.1056/nejmoa1915932, indexed in Pubmed: 32757521.
- Gold MR, Lambiase PD, El-Chami MF, et al. UNTOUCHED Investigators*. Primary results from the understanding outcomes with the S-ICD in primary prevention patients with low ejection fraction (UNTOUCHED) trial. *Circulation.* 2021; 143(1): 7–17, doi: 10.1161/CIRCULATIONAHA.120.048728, indexed in Pubmed: 33073614.
- McLeod CJ, Boersma L, Okamura H, et al. The subcutaneous implantable cardioverter defibrillator: state-of-the-art review. *Eur Heart J.* 2017; 38(4): 247–257, doi: 10.1093/eurheartj/ehv507, indexed in Pubmed: 28182222.
- Bordachar P, Marquié C, Pospiech T, et al. Subcutaneous implantable cardioverter defibrillators in children, young adults and patients with congenital heart disease. *Int J Cardiol.* 2016; 203: 251–258, doi: 10.1016/j.ijcard.2015.09.083, indexed in Pubmed: 26519678.
- Brugada J, Blom N, Sarquella-Brugada G, et al. European Heart Rhythm Association, Association for European Paediatric and Congenital Cardiology. Pharmacological and non-pharmacological therapy for arrhythmias in the pediatric population: EHRA and AEPCC-Arrhythmia Working Group joint consensus statement. *Europace.* 2013; 15(9): 1337–1382, doi: 10.1093/europace/eut082, indexed in Pubmed: 23851511.
- Silvetti MS, Pazzano V, Verticelli L, et al. Subcutaneous implantable cardioverter-defibrillator: is it ready for use in children and young adults? A single-centre study. *Europace.* 2018; 20(12): 1966–1973, doi: 10.1093/europace/euy139, indexed in Pubmed: 29939256.
- Lewandowski M, Syska P, Kowalik I. Children and young adults treated with transvenous and subcutaneous implantable cardioverter-defibrillators: a 22-year single-center experience and new perspectives. *Kardiol Pol.* 2020; 78(9): 869–874, doi: 10.33963/KP.15469, indexed in Pubmed: 32631024.
- Priori SG, Blomström-Lundqvist C, Mazzanti A, et al. ESC Scientific Document Group. 2015 ESC Guidelines for the management of patients with ventricular arrhythmias and the prevention of sudden cardiac death: The Task Force for the Management of Patients with Ventricular Arrhythmias and the Prevention of Sudden Cardiac Death of the European Society of Cardiology (ESC). *Eur Heart J.* 2015; 36(41): 2793–2867, doi: 10.1093/eurheartj/ehv316, indexed in Pubmed: 26320108.
- Winter J, Shin D-I, Siekiera M, et al. Abstract 14479: first experiences in children and young adults with a totally subcutaneous implantable cardioverter defibrillator system. *Circulation.* 2012; 126(Suppl 21): A14479.
- van Rees JB, de Bie MK, Thijssen J, et al. Implantation-related complications of implantable cardioverter-defibrillators and cardiac resynchronization therapy devices: a systematic review of randomized clinical trials. *J Am Coll Cardiol.* 2011; 58(10): 995–1000, doi: 10.1016/j.jacc.2011.06.007, indexed in Pubmed: 21867832.
- Link MS, Hill SL, Cliff DL, et al. Comparison of frequency of complications of implantable cardioverter-defibrillators in children versus adults. *Am J Cardiol.* 1999; 83(2): 263–266, A5-6, doi: 10.1016/s0002-9149(98)00834-0, indexed in Pubmed: 10073833.
- Maisel WH, Moynahan M, Zuckerman BD, et al. Pacemaker and ICD generator malfunctions: analysis of Food and Drug Administration annual reports. *JAMA.* 2006; 295(16): 1901–1906, doi: 10.1001/jama.295.16.1901, indexed in Pubmed: 16639048.
- Bogush N, Espinosa RE, Cannon BC, et al. Selecting the right defibrillator in the younger patient: Transvenous, epicardial or subcutaneous? *Int J Cardiol.* 2018; 250: 133–138, doi: 10.1016/j.ijcard.2017.09.213, indexed in Pubmed: 29169751.
- Brisben A. How the S-ICD (subcutaneous implantable cardiac defibrillator) senses cardiac signals to minimize cardiac over-sensing and maximize rhythm discrimination. *J Electrocardiol.* 2018; 51(6S): S38–S43, doi: 10.1016/j.jelectrocard.2018.08.022, indexed in Pubmed: 30220546.
- Kaczmarek K, Kałowski M, Krzysztof Wrzanic J, et al. Conventional and alternative preimplantation ECG screening for subcutaneous ICD in high risk hypertrophic cardiomyopathy patients. *J Electrocardiol.* 2020; 58: 68–73, doi: 10.1016/j.jelectrocard.2019.11.044, indexed in Pubmed: 31770668.