JACC: CLINICAL ELECTROPHYSIOLOGY VOL. ■, NO. ■, 2018

PUBLISHED BY ELSEVIER

Value of Regular Defibrillation Threshold Testing After Extracardiac Implantable Cardioverter Defibrillator Placement in Small Children During Mid-Term Follow-Up

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ABSTRACT

OBJECTIVE The purpose of this study was to analyze course of defibrillation threshold (DFT) with growth.

BACKGROUND Data on regular DFT testing after extracardiac implantable cardioverter defibrillator (ICD) placement in infants and small children is still limited.

METHODS An extracardiac ICD was placed in 23 pediatric patients (median age 6.1 years; median body weight 21 kg, median length 120 cm). The defibrillator lead was tunneled pleurally, and the device was placed as "active can" in the right upper abdomen or in a horizontal position between the diaphragm and the pericardium, respectively. DFT was verified intraoperatively, 3 months later, and every 12 months thereafter. The aim was to achieve DFT <15 J allowing ICD programming with a double safety margin above DFT.

RESULTS In all 23 patients, an intraoperative DFT <15 J could be accomplished. Serial DFT testing showed an increase from a median DFT of 10 J intraoperatively to 15 J after 1 year. During mean follow-up of 2.0 years, a significant correlation between DFT and body length, but not body weight, was observed. In 4 of 23 (17%) patients, surgical revision was required because of a DFT increase >20 J during regular DFT testing. No complications regarding DFT testing were noted.

CONCLUSIONS After extracardiac ICD placement in infants and small children, DFT increase related to body length was evident during mid-term follow-up. Routine serial DFT testing was a safe procedure and identified a significant DFT increase in 4 of 23 patients. Serial DFT testing during follow-up in these patients is recommended.
(J Am Coll Cardiol EP 2018;■:■-■) © 2018 by the American College of Cardiology Foundation.

Until now, placement of implantable cardioverter defibrillators (ICDs) in children and adolescents was a rare procedure compared with its more frequent use in the adult population. However, despite a 3-fold increase in pediatric ICD placement from 1997 to 2006 (1), ICD use in children with primary electrical disease has tapered off significantly over the past decade owing to many factors, but the most important is that we know how to better risk-stratify these children. ICD placement in infants and small children accounts for less than 1% of total ICDs (2).

The majority of ICD placements in older children and adolescents with biventricular hearts have

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All authors attest that they are in compliance with human studies committees and animal welfare regulations of the authors' institutions and Food and Drug Administration guidelines, including patient consent where appropriate. For more information, visit the *JACC: Clinical Electrophysiology* author instructions page.

Manuscript received October 6, 2016; revised manuscript received March 5, 2018, accepted March 15, 2018.

ISSN 2405-500X/$36.00 https://doi.org/10.1016/j.jacep.2018.03.012

ABBREVIATIONS AND ACRONYMS

DFT = defibrillation threshold

ICD = implantable cardioverter defibrillator

devices implanted using the transvenous route. There is, however, still no established concept for implantation in infants and small children. Recently, the subcutaneous ICD (S-ICD) was introduced into clinical practice. Because of the size of the S-ICD, this system is not suitable for use in small children, as there is an increased risk of erosion or wound dehiscence. In addition, sensing problems with inappropriate discharges as well as delayed detection of ventricular fibrillation have been reported (3).

During the last decade, a variety of implantation techniques have been introduced into clinical practice for ICD placement in infants and small children as well as in patients with congenital heart defects lacking venous access to the heart. Up to now, there has been only a limited number of studies covering more than 3 patients (4-10). Surgical techniques applied varied in positioning of the shock electrode and the device and procedures were accomplished by open thoracotomy and minimal invasive procedures, respectively. However, follow-up data after ICD placement using these novel techniques is still limited. In addition, course of DFT has not been reported in the majority of these studies, which is, however, of paramount importance with respect to further growth and safety of the patients, as shift of the electrical field and shock vector may be inferred.

In 2006, we reported our initial data on the extracardiac ICD-placement technique using a subcutaneous position of the shock electrode and insertion of the device within the right anterior abdominal wall (10). During further post-operative course, we had, however, to observe need for surgical revisions in almost all patients (83%) during a mean follow-up of 2.9 years due to dislocation or fracture of the shock electrode. Therefore, in 2009, we changed our implantation technique to a pleural position of the shock electrode, as early data from other centers applying this technique were promising (4,11). Follow-up data, however, are sparse.

The purpose of the current study was therefore to analyze safety and efficacy by serial DFT assessment in a considerable number of patients over mid-term follow-up.

METHODS

PATIENTS. From 2007 to 2014, an ICD was placed using a defibrillation coil in the pleural space in 23 patients with body weight <40 kg, including 3 patients with former subcutaneous systems (10). In these 3 patients, the system had failed because of dislocation and fracture of the ICD coil in 2 patients and battery depletion in the remaining patient. The subcutaneous coil was completely removed in these patients. Median age of the study patients was 6.1 ± 3.3 (0.2 to 11.5) years, median body weight was 21.0 ± 9.6 (4.5 to 39.0) kg, and median body length was 120.0 ± 26.5 (61 to 147) cm. The case report of 1 patient in this series had been published previously (12). The study protocol was approved by the institutional committee of Göttingen Heart Center.

Patients' diagnoses are illustrated in **Figure 1**. ICD placement was performed in 12 patients for primary prevention and in 11 patients for secondary prevention, according to current guidelines (13,14). Patients received additional antiarrhythmic medication, depending on their underlying disease.

SURGICAL TECHNIQUE. In all study patients, a modification of the technique as reported by Bauersfeld et al. (4) was applied. During general anesthesia, the defibrillation lead (Medtronic Transvene 6937 SN, 35 or 52 cm, coil length 8 cm; Medtronic Inc., Minneapolis, Minnesota) was inserted into the pleural space via a small left lateral thoracotomy within the 4th intercostal space until almost reaching the vertebral column and was secured with several sutures. The proximal end of the electrode was fixated to the anterior thoracic wall with the anchoring sleeve. Bipolar steroid eluting epicardial sensing and pacing leads (Capsure Epi 4968; 25 or 35 cm; Medtronic Inc.) were sutured to the ventricular myocardium, and atrial myocardium in selected patients who needed dual-chamber pacing and/or sensing.

Until 2008, the generator (Virtuoso VR D 164, Secura VR D 234, Protecta VR D 364 or XT DR 354, Medtronic Inc.) was placed in the right upper abdominal wall as described in our first series (10). Since 2009, the generator was inserted in a horizontal position between the diaphragm and the pericardium (**Figure 2**) via a subxiphoid incision. In these patients, the shock electrode and the sensing and pacing leads were tunneled under the left costal arch and connected to the device. Finally, the device was fixated at the right or left costal arch to prevent migration.

INTRAOPERATIVE DFT ASSESSMENT. Sensing and pacing thresholds, as well as electrode impedances, were determined. The defibrillation electrode was used as cathode and the "active can" device as anode. For the purpose of this study, the aim was to achieve a DFT <15 J, allowing ICD programming with a double safety margin above DFT.

Ventricular tachycardia or fibrillation was induced by ventricular burst pacing or T-wave shocks. DFT