Patients with congenital heart disease: how to determine the eligibility for implantation of a subcutaneous implantable defibrillator?

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This editorial refers to ‘Potential eligibility of congenital heart disease patients for subcutaneous implantable cardioverter-defibrillator based on surface electrocardiogram mapping’ by M. Zeb et al., on page 1059–1067.

The clinical value of the implantable cardioverter-defibrillator (ICD) in reducing sudden cardiac death has been proved in selected patients with ischaemic or non-ischaemic cardiomyopathy. Since the introduction of the ICD in the 1980s, the technology has evolved from an epicardial to a transvenous approach.1 Recently, the subcutaneous cardioverter-defibrillator (S-ICD) has been added to the armamentarium of treatment to prevent sudden cardiac death.2,3 Although the S-ICD shares with conventional ICDs the key functions of detecting and defibrillating malignant ventricular arrhythmias, it represents a major departure in terms of design and functionality. Being totally subcutaneous, it is devoid of risks associated with transvenous leads; vascular obstruction, systemic infection, insulation breaches and conductor breaks, and risks associated with transvenous lead extraction if required.

The S-ICD system delivers non-programmable 80-J biphasic transthoracic shocks and has the capability to provide ventricular bradycardia pacing up to 30 s post-shock at a rate of 50 bpm. The S-ICD cannot provide pacing for bradycardia, cardiac resynchronization therapy or antitachycardia pacing. For arrhythmia detection and discrimination, the S-ICD system utilizes one of the three subcutaneous ECGs recorded between two sensing electrodes or between a sensing electrode and the pulse generator.

Inappropriate shock delivery is an important adverse event with all implantable defibrillators. The rate of inappropriate shocks with the S-ICD was 13.1% over 11 months in the study by Weiss et al.2 and an annual rate of 7% in the EFFORTLESS (Evaluation of FactORS ImpacTing CLinical Outcome and Cost EffectiveneSS) S-ICD registry,4 somewhat higher than that has been reported for transvenous ICDs: 11.5% over 20 months in the MADIT-II (Multicenter Automatic Defibrillator Implantation Trial) study.5

The mechanism of inappropriate shocks is different between S-ICD and conventional defibrillators. The rate of inappropriate shocks for supraventricular arrhythmias is low with S-ICD and in the START (subcutaneous vs. transvenous arrhythmia recognition testing) study, a head-to-head comparison between S-ICD and contemporary transvenous ICD systems, demonstrated superiority of S-ICD with regard to specificity for supraventricular arrhythmia discrimination.6 However, subcutaneous rhythm analysis is confounded by T-wave oversensing, which is the most common cause of inappropriate shocks with this device.3,4 In order to avoid inappropriate shocks due to T-wave oversensing, a pre-implant surface ECG screening template is used to identify patients who are likely to have an unsuitable subcutaneous ECG.

Who should receive an S-ICD device? Clearly, patients who have a pacing requirement are not eligible. Fortunately, most ICD recipients do not have a pacing indication and can receive either a subcutaneous or transvenous device. Implantation of an ICD in a young person requires careful consideration as to the most suitable device. Young patients are likely to have their device for decades and are at the highest risk of device complications. When considering patients with congenital heart disease (CHD), ICD implantation can be challenging due to congenital venous anomalies, surgical obstacles (patches, conduits, and baffles), and ventricular geometry and position. With contemporary transvenous ICD systems, these patients are exposed to the near certainty of lead failure and the need for lead revision, and the hazards of either multiple intravascular leads or lead extraction. From this perspective, patients with CHD may be a target population for S-ICD placement when they have no pacing indication.

Zeb et al.7 have explored the surface ECG characteristics in three groups of CHD patients (surgically corrected transposition of the...
great arteries, tetralogy of Fallot, and single ventricle with Fontan repair). The aim of their study was to determine the proportion of CHD patients who fulfil the requirement for rhythm discrimination of S-ICD using the proprietary screening tool. They rigorously studied 10 patients in each group and a further 10 controls. Screening the three vectors that the device can detect in six postures, they determined eligibility for subcutaneous defibrillator implantation. They found that using the manufacturers recommended screening in two postures (erect and supine), an adequate sensing vector was obtained in 26 of the 30 patients and all controls. The addition of screening in six postures would have rendered one patient and one control ineligible for device implantation. Furthermore, whilst the primary vector (equivalent to screening ECG lead III) was most suitable in controls, in a greater proportion of patients with CHD, the alternate vector (equivalent to screening ECG lead I) was more suitable, presumably due to the effect of CHD on the QRS and T-wave vectors.

This study reassures us that the majority of patients with surgically corrected CHD, at least of the type studied, are eligible for implantation of S-ICD. Furthermore, the eligibility of patients with surgically corrected CHD is comparable with the general ICD population at $\sim 85\%$. However, pre-implantation screening does not eliminate the risk of T-wave oversensing with the subcutaneous defibrillator. Young patients appear to be at greater risk, especially patients with hypertrophic cardiomyopathy. Once S-ICD is implanted, T-wave oversensing can be identified using exercise testing and reduced with reprogramming vectors or therapy zones. Future development of S-ICD systems will likely reduce the risk in the future. In the current device upgrades to the detection algorithm have already been introduced, with further development likely. In the longer term, the device has the theoretical capacity to monitor all three sensing vectors, which should further enhance sensing discrimination. Another option would be the ‘marriage’ of an S-ICD device with a leadless pacemaker to combine the advantages of S-ICD with endocardial or mixed sensing, without the need for transvenous leads.

The S-ICD device has already proved itself to be a viable alternative to the transvenous ICD. Although it has issues with inappropriate shocks due to T-wave oversensing, it should be remembered that the current device is a first-generation device, and as such it has performed exceptionally well. Further development of the device and a clearer understanding of appropriate screening and patient selection can only improve its real life performance, and cement its place in the armamentarium of treatment to prevent sudden cardiac death.

References