First clinical evaluation of subcutaneous implantable cardiac defibrillator in Brugada patients

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Background: Brugada syndrome (BrS) is an inherited arrhythmia syndrome with an increased risk of SCD. While Subcutaneous ICD (S-ICD) is a seductive approach to treat these patients, questions raised on the risk of inappropriate shock in this specific population.

Objective: The aim of this study was to evaluate the safety and the effectiveness of the S-ICD in BrS patients.

Methods: We prospectively enrolled 112 BrS patients implanted with S-ICD in 17 European centers. During the screening at least 2 vectors must be suitable but it was not necessary to check for the suitability of the ECG during sodium channel blocker or exercise test. S-ICD indications follow the current guidelines.

Results: Mean age of patients was 45 ± 13 years, with 95 (85%) males. Implantation was performed in 91 (83%) patients for primary prevention and in 18 (16%) patients for secondary prevention. There is an indication of ICD replacement for 16 patients (14%): 13 lead defect (81%), 1 infection (6%) and 2 ICD end of life (13%). In this cohort, 57 patients (51%) had spontaneous type I BrS, 60 patients (55%) were symptomatic: 10 resuscitated SCD (17%) and 48 (83%) syncope.

Implantation was performed under general anesthesia in 79 patients (71%). The mean operation time was 56+/−19 min. The lead was placed at the left side of the sternum in 102 patients (92%) and at the right side in 9 (8%). Sensing configuration was the primary vector for 46 patients (41%), secondary vector for 57 (51%) and alternative vector for 9 (8%). No complications occurred during implantation.

During a mean follow-up of 15.6 months (0-39 months), 6 patients (5%) had at least one appropriate shock (n=9). The rate of appropriate shock was 4.5%/y. All the VF episodes were successfully treated with the first shock. One patient had VF ablation for recurrent VF. Among the 6 patients who received an appropriate shock, 3 (50%) were implanted for secondary prevention and 3 (50%) were implanted for primary prevention including 2 patients with a history of syncope and one asymptomatic patient.

Twelve patients (11%) had at least one inappropriate shock (n=22) including 2 patients with respectively 8 and
4 inappropriate shocks due to T-wave oversensing. With the SMART pass system the first patient had no more inappropriate shock for now 2 years. The rate of inappropriate shock was 9%/y. One patient died of myocardial infarction.

Five patients (4%) were hospitalized for complications (4 pocket or scar infections and 1 electrode failure).

Conclusion:

Our initial experience showed that S-ICD is efficient to treat VF episode in BrS patients. In this population, the rate of inappropriate shock was 9%/y. In view of these results, S-ICD implantation seems to be efficient to protect BrS patients against SCD.