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Primary prevention of sudden cardiac death in patients with tetralogy of Fallot with implantable cardioverter defibrillator: insights from the DAI-T4F study

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Background

Ventricular arrhythmias and sudden death are feared late complications in patients with tetralogy of Fallot. Selection of candidates for primary prevention implantable cardioverter defibrillator (ICD) remains challenging in this population. Non-sustained ventricular tachycardia (NSVT), altered left ventricular ejection fraction (LVEF), positive programmed ventricular stimulation, and enlarged QRS are currently used for risk stratification.

Purpose

To identify high-risk patients with tetralogy of Fallot in the setting of primary prevention of sudden cardiac death.

Methods

The DAI-T4F study is a large ongoing national French registry including all patients with tetralogy of Fallot and ICD (NCT03837574). Information have been collected prospectively since 2010 with annual update. Baseline patient characteristics and clinical events during the follow-up were analyzed with central adjudication. Cox proportional hazard models were used to identify factors associated with appropriate ICD therapies.

Results

Among 134 patients enrolled, 47 (35.1%) underwent ICD implantation for primary prevention (median age 49.1 years, 76.6% males). At baseline, 20 (42.6%) patients had NSVT, 17 (36.2%) had severe altered LVEF =35%, 16 (34.0%) had positive programmed ventricular stimulation, and 16 (34.0%) had QRS duration = 180ms. Overall, 20 (42.6%), 15 (31.9%), and 6 (12.8%) patients had respectively one, two, or = three of these risk factors. Six (12.8%) patients were implanted for other indications. During a median (IQR) follow-up duration of 5.3 (2.1-8.0) years, 14 (29.8%) patients had at least one appropriate ICD therapy. The annual incidence of appropriate ICD therapies were 2.8%, 4.6%, 6.3%, and 8.6% in patients with none, one, two, or = three of these factors (p for trend = 0.145). None of predictors, considered isolated, was significantly associated with ICD appropriate therapies. Patients with non-sustained ventricular tachycardia (NSVT) and...
positive programmed ventricular stimulation had a significant increased risk of ICD appropriate therapies (HR=3.8, 95% CI: 1.1-14.3, p=0.035), as well as patients with NSVT and QRSd = 180 ms (HR=7.2, 95% CI: 1.6-32.7, p=0.003). No patient with severe altered LVEF without other risk factor had appropriate ICD therapy. Patients with congestive heart failure and/or altered LVEF had a higher risk of non-sudden death or cardiac transplantation (HR=14.4, 95% CI: 1.8-112.7, p<0.001). Seventeen (36.2%) patients experienced at least one ICD-related complication.

Conclusions

Our data illustrate that specific risk stratification and primary prevention for sudden cardiac death in patients with tetralogy of Fallot may be improved. The value of a severely altered LVEF appears low in the absence of other risk factors, and combination of different predictors is essential. The high rate of complications as well as consideration of competing risk situation have to be integrated in the benefit-risk equation.