

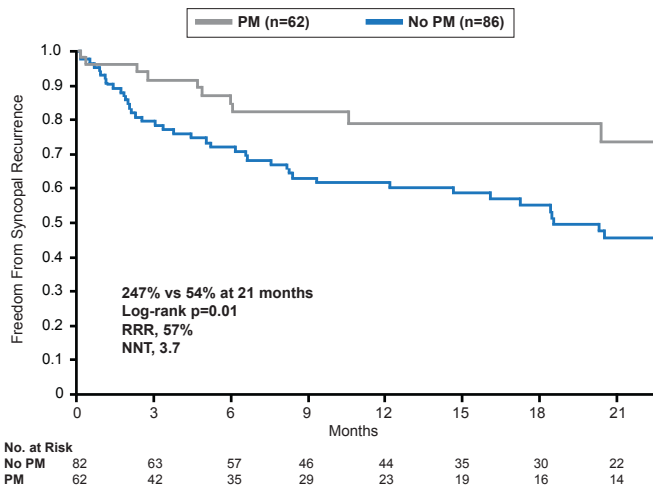


## CLINICAL TRIAL HIGHLIGHTS

Atrial tachyarrhythmia was associated with intrinsic cardiac syncope, as 38% of patients with intrinsic cardiac arrhythmias versus 5% of NMS patients had atrial tachyarrhythmias. Other multiple factors related to syncopal events and other factors, such as tilt testing, structural heart disease, hypertension, diabetes, and concomitant medications, were found not to be associated with intrinsic cardiac syncope.

In NMS patients that received pacemaker therapy (n=62), 27% experienced recurrence of syncope, compared with 54% of NMS patients that did not receive a pacemaker at 21 months, resulting in a hazard ratio of 57% (p=0.01; Figure 1). The median total number of syncopal events was predictive of recurrence (p=0.007) and patients with ≥8 syncopal events were more likely to experience a recurrence (p=0.001).

Figure 1. Effect of Pacemaker Therapy in Patients With NMS

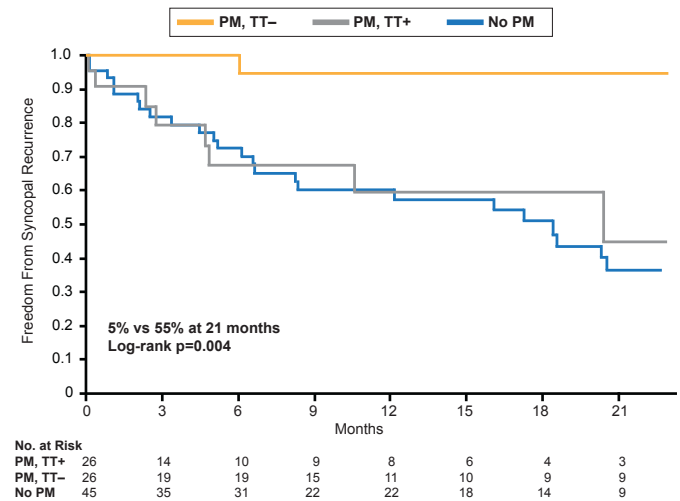


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In NMS patients, a positive tilt test occurred in 89% of patients that developed recurrence compared with 42% (p=0.0004) in patients that did not develop recurrence following pacemaker therapy. In NMS patients with a pacemaker, 5% that had a negative tilt test experienced recurrence compared with 55% of patients that had a positive tilt test (p=0.004; Figure 2).

Prof. Brignole concluded that in his opinion, the data from the ISSUE-3 trial suggest that pacemaker therapy is beneficial in the subset of NMS patients that receive a negative result during the tilt test. However, cardiac pacing does not appear have efficacy in patients that have a positive tilt test.

Figure 2. Tilt Test Results Are Predictive of Syncope Recurrence Following Pacemaker Therapy



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## Radiofrequency Ablation Without ICD Effective and Safe for Well-Tolerated SMVT

Written by Toni Rizzo

Patients with structural heart disease (SHD) who experience sustained monomorphic ventricular tachycardia (SMVT) are usually considered to have a poor prognosis. According to the American College of Cardiology (ACC)/American Heart Association (AHA)/Heart Rhythm Society (HRS) 2008 Guidelines for device-based therapy of cardiac rhythm abnormalities, therapy with an implantable cardioverter defibrillator (ICD) is indicated in patients with SMVT and SHD [Epstein AE et al. *Circulation* 2008]. The ACC/AHA/European Society of Cardiology (ESC) 2006 Guidelines recommend ablation for patients with SMVT who are at low risk for sudden cardiac death (SCD) [Zipes DP et al. *Circulation* 2006]. a condition which “a priori” does not correspond to patients with structural heart disease.

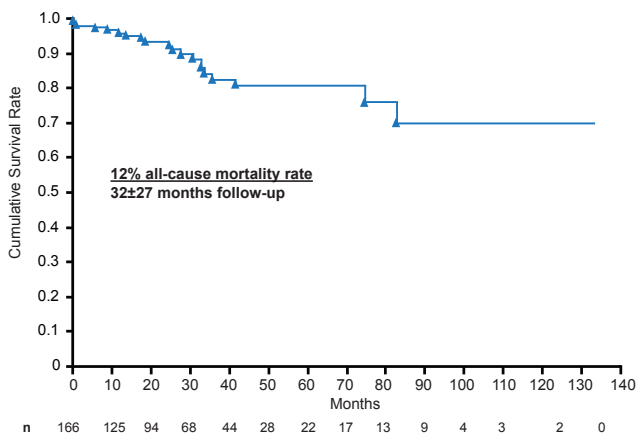
Philippe Maury, MD, University Hospital Rangueil, Toulouse, France, reported the results of the Radio-Frequency Ablation as a primary management for Sustained Monomorphic Ventricular Tachycardia in Patients With Structural Heart Disease (ie, without implantation of a defibrillator). The investigators hypothesized that these patients would have a favorable prognosis and that any recurrences would not result in death.

The study included 166 consecutive patients with SHD treated with radiofrequency ablation (RFA) without an ICD for well-tolerated SMVT, defined as a lack of syncope or cardiac collapse at the time of VT and an ejection fraction (EF) >30%. The control group consisted of patients from the Antiarrhythmics Versus Implantable Defibrillators registry [AVID; Raitt MH et al. *Circulation* 2001].

Of the 166 patients, 93 (56%) presented with palpitations only, 35 (21%) with presyncope, 24 (14%) with congestive heart failure, and 15 (9%) with chest pain. A total of 187 ablations were performed. Following ablation, VT was not inducible in 137 of 158 patients (87%), while 21 patients (13%) had inducible VT (6 clinical, 15 nonclinical). Complications occurred in 11 patients (6.5%), including pericardial effusion (n=1), tamponade (n=3), groin hematoma (n=4), femoral pseudo-aneurysm (n=1), and atrioventricular block (n=2). There were no deaths directly related to the procedure. At discharge, patients were prescribed  $\beta$ -blockers (43%), amiodarone (5%), amiodarone plus a  $\beta$ -blocker (17%), sotalol (10%), a Class 1 antiarrhythmic (3%), or no drug (22%).

At a follow-up of 32 $\pm$ 27 months, 20 patients (12%) had died (4.5% annual rate), including 8 (40%) noncardiovascular deaths, 4 (20%) sudden deaths, and 8 (40%) nonarrhythmic cardiovascular deaths (Figure 1). The cumulative sudden death rate was 2.4%. None of the patients who died suddenly had recurrent VT before death.

Figure 1. Cumulative Survival at 32 $\pm$ 27 Months Follow-Up

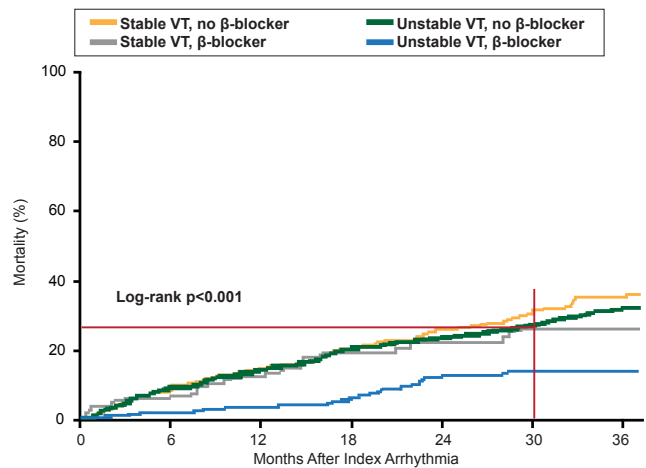


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In comparison, 30-month all-cause mortality in the similar patients from the AVID trial control group [Raitt MH et al. *Circulation* 2001] was >20% (Figure 2).

During follow-up, 27 patients (16%) had recurrent VT (6% annual rate; Figure 3). Among these patients, 5 had received an ICD only, 14 had ablation (followed by an ICD in 6 of 14), and 8 did not have ablation or an ICD.

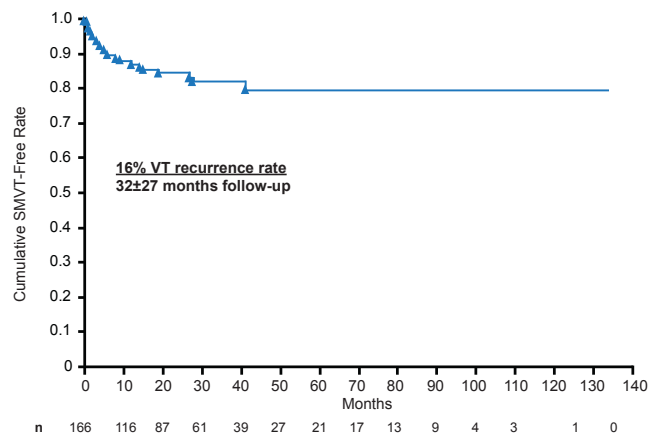
Figure 2. AVID Registry All-Cause Mortality at 30 Months



VT=ventricular tachycardia.

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Figure 3. Cumulative SMVT-Free Rate at 32 $\pm$ 27 Months



SMVT=sustained monomorphic ventricular tachycardia; VT=ventricular tachycardia.

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Prof. Maury concluded that primary RFA for well-tolerated SMVT in patients with SHD and non severely depressed EF, without ICD implantation, is effective and is not associated with a significant risk of late sudden death. However, this was a retrospective multicenter study with a variety of ablation procedures and endpoints, and with a mean follow-up of only 30 months. Prospective randomized trials are needed to evaluate RFA versus ICD in patients with SHD and SMVT.