CLINICAL TRIAL HIGHLIGHTS

The limitations of this device include the lack of visual guidance for locating the fossa ovalis and performing a transseptal puncture. The risk-benefit trade-off was also difficult to assess. Follow-up in this study is ongoing and will be reported at a later date; however, the preliminary findings support the further study of an atrial transseptal LVE lead system implanted from a single pectoral incision in patients who otherwise have limited CRT options.

Substrate-Based Ablation Reduces Recurrent Arrhythmia Compared to Focused Ablation in Ischemic Cardiomyopathy With Stable VT

Written by Emma Hitt, PhD

Substrate-based ablation of ventricular tachycardia (VT) in patients with ischemic cardiomyopathy resulted in fewer VT recurrences and less rehospitalization compared with the conventional clinical VT ablation. Luigi Di Biase, MD, PhD, Texas Cardiac Arrhythmia Institute, Austin, Texas, USA, and Albert Einstein College of Medicine, Bronx, New York, USA, presented data from the Ablation of Clinical Ventricular Tachycardia Versus Addition of Substrate Ablation on the Long-term Success Rate of VT Ablation trial [VISTA; NCT01045668].

Patients with ischemic cardiomyopathy and stable monomorphic VT may undergo catheter ablation as an option to reduce implantable cardiac defibrillator shocks. However, it is unclear if ablation of the clinical stable VT or more extensive substrate-based ablation is more beneficial. The purpose of the VISTA trial was to determine whether substrate-based ablation improved outcomes compared with the conventional ablation of the stable clinical VTs.

In the open-label, randomized, parallel-group multicenter VISTA trial, 128 patients with symptomatic, drug-refractory, hemodynamically stable VTs after coronary artery disease were randomly assigned to undergo clinical stable VT ablation or substrate ablation. Every 3 months, patients were assessed by implantable device interrogations and examination during office visits. Baseline characteristics were similar between both study arms, with the mean age ranging from 65 to 67 years and with most patients being men (93%) with hypertension (72% to 76%) or diabetes (32% to 42%). In addition, the mean left ventricular ejection fraction (LVEF) was 32% to 33%, and 33% to 35% had previously undergone coronary artery bypass graft surgery.

The primary endpoint of the VISTA trial was recurrence of any VTs over the 12-month period following ablation. Recurrence was defined as any arrhythmia that required device-based treatment or any VT event that occurred during clinical evaluation. The secondary end points included periprocedural complications and postprocedural mortality and rehospitalization at 12 months.

At 12 months, 51.7% of patients who underwent clinical VT ablation achieved freedom from any recurrent VTs, compared with 84.5% of patients who underwent substrate ablation (log-rank p<0.001; Figure 1). In addition, significantly more patients who underwent clinical VT ablation required rehospitalization (32%) than those patients who underwent substrate ablation (12%; p=0.014). Overall mortality in the VISTA trial was 11.9%, with mortality occurring in 15% of patients who underwent substrate ablation (p=0.21).





VT=ventricular tachycardia.

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In addition, use of the clinical VT ablation method was associated with a greater rate of VT recurrence, with a hazard ratio of 3.84 (p=0.001). Interestingly, other risk factors that were associated with VT recurrence were diabetes (HR, 3.11; p=0.02), LVEF (HR, 0.77; p=0.035), electrical storm (HR, 1.86; p=0.043), male sex (HR, 3.23; p=0.029), and age per 5-year increase (HR, 1.11; p=0.016). Clinical VT ablation (HR, 3.1; p=0.01) and diabetes (HR, 2.75; p=0.042) remained independent predictors of VT recurrence after adjustment for covariates based on a Cox multivariate model.

Complications of ablation included 1 atrial valve fistula in the clinical VT ablation group and 5 pericardial

effusions (2 in the clinical VT ablation group and 3 in the substrate ablation group).

Dr. Di Biase stated that, in his opinion, the data from the randomized VISTA trial indicate that substrate-based ablation may be superior to clinical VT ablation in patients with ischemic cardiomyopathy with stable VT. However, he noted that additional studies are needed to confirm the results of the VISTA trial.

Adenosine-Guided Elimination of Dormant PV Conduction in Paroxysmal AF

Written by Emma Hitt, PhD

Adenosine-guided elimination of dormant pulmonary vein (PV) conduction decreases recurrence of atrial tachyarrhythmias (ATs) in patients undergoing catheter ablation for paroxysmal atrial fibrillation (AF). Laurent Macle, MD, Montreal Heart Institute, Montreal, Canada, presented data from the Adenosine Following Pulmonary Vein Isolation to Target Dormant Conduction Elimination trial [ADVICE; NCT01058980].

Following catheter ablation, up to 50% of patients experience recurrence of AF, which is often a result of the recovery of PV conduction. The need for additional ablation can be determined with adenosine, as the agent is able to unmask dormant conduction after PV ablation. However, the effect of an adenosine-guided AF ablation strategy on the prevention of arrhythmia recurrence is unknown. The purpose of the ADVICE trial was to evaluate the effect of adenosine-guided ablation on the long-term efficacy of PV isolation in patients with paroxysmal AF.

In the multicenter single-blind Phase 4 ADVICE trial, 534 patients undergoing radiofrequency catheter ablation were studied. Following PV isolation, dormant PV conduction was assessed with intravenous adenosine. If dormant conduction was elicited, patients were randomly assigned to no further ablation or to additional adenosine-guided ablation until dormant conduction was abolished. If no dormant conduction was revealed, randomly selected patients were followed in a registry.

The primary endpoint was time to first recurrence of symptomatic electrocardiogram-documented AT \geq 30 seconds between Day 91 and Day 365 following ablation or any repeat ablation procedure. Major secondary endpoints included time to first recurrence of any electrocardiogram-documented AT, antiarrhythmic drug use, repeat ablation for recurrent AT, and major complications.

The median dose of adenosine used for the assessment of dormant PV conduction was 12 mg. Dormant conduction was present in 53% of patients and 21% of PVs. In the additional ablation arm, 95% of patients experienced successful elimination of dormant conduction.

Among patients with dormant PV conduction, a significantly greater number who received additional targeted ablation achieved event-free survival (freedom from symptomatic AT) compared with patients who received no further ablation (HR, 0.44; 95% CI, 0.31 to 0.64; p<0.0001; Figure 1). Event-free survival occurred in 69.4% of patients with dormant conduction randomly assigned to additional targeted ablation, 55.7% without dormant conduction, and 42.3% with dormant conduction randomly assigned to no further ablation.





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*On November 21, 2014, this was changed from Dornmant to Dormant. **On November 21, 2014, this was changed from Dormarnt to Dormant.

In addition, patients with dormant conduction who were randomly assigned to additional targeted ablation showed greater event-free survival in terms of any AT, with and without the use of antiarrhythmic drugs. Repeat ablation for recurrent AT was required in 35% of patients with dormant conduction who did not receive further ablation, compared with 20.4% of patients who had dormant conduction and received additional targeted ablation and 27.4% patients who did not have dormant conduction. Serious adverse events occurred in 7.2% of patients, and the rate was similar among all study arms.

In conclusion, Dr. Macle stated that, in his opinion, the data from the ADVICE trial indicate that elimination