LVE Lead Placement Using a Superior Approach Is Feasible and Safe

Written by Phil Vinall

The Alternate Site Cardiac Resynchronization study [ALSYNC; NCT01277783] investigated the safety and efficacy of left ventricular endocardial (LVE) pacing using a novel atrial transseptal system for lead delivery. John M. Morgan, MD, University of Southampton, Southampton, United Kingdom, reported that using a lead delivery system with a single pectoral incision for LVE pacing is both safe and feasible.

The benefits of cardiac resynchronization therapy (CRT) have been well established; however, approximately 10% of patients are not able to undergo device implantation because of procedural failures [Cleland JG et al. *Eur Heart J* 2013]. In addition, approximately, 30% of patients fail to respond to biventricular pacing [Sohaib SMA et al. *Eur J Heart Fail* 2013]. LV endocardial pacing has the benefit of being a predictable procedure that allows a wide choice of left ventricular surface for pacing, with the potential for an improved CRT response. Challenges to the implementation of this approach include the need for safe and simple implantation tools and the need to better understand and control potential complications. The model 3830 system is composed of a deflectable catheter-in-catheter with a radiofrequency-powered transseptal puncture guidewire and dilator, which enable a subclavian approach and targeted LVE lead delivery.

ALSYNC was a noncomparative, nonrandomized, prospective clinical study conducted at 16 European and 2 Canadian centers. The primary objective was survival of LVE lead and delivery system–related complications at 6 months. Complications were defined as adverse events resulting in death, confirmed stroke, termination of significant device function, or invasive intervention. There was a minimum of 12 months' follow-up, with visits at 1, 3, 6, and 12 months and biannually after 12 months.

Eligible patients were candidates for CRT in whom prior coronary sinus left ventricular lead implantation had failed, those with suboptimal coronary sinus anatomy, and those who were nonresponders after ≥6 months of CRT. Subjects also had to be able to take oral vitamin K antagonists (international normalized ratio of 2 to 4 with a target of 3). The study comprised 138 subjects with a median age of 68 years; 22.5% were CRT nonresponders, 50% had atrial fibrillation, 78% had undergone failed prior implantation, and 76.1% were on anticoagulants. Most subjects were in New York Heart Association class III (68.1%) or IV (7.2%).

The primary end point occurred in 23 patients (25 total events) during the first 6 months after the procedure. There were 2 strokes during the first 6 months, neither of which was disabling (Rankin score < 3). Four transient ischemic attacks were reported during the first 6 months, 1 of which did not meet the criteria for the primary end point. Ten patients died during the 6 months of follow-up; only 1 death was related to the implantation procedure. Mitral regurgitation improved in the majority of subjects. In the subgroup of subjects originally considered nonresponders, between 50% and 60% responded to LVE therapy. Clinical outcomes are shown in Table 1.

Table 1. Clinical Outcomes at 6 Months

		ALSYNC Study		
CRT Outcome		All Patients	Patients With Failed Implantation	Patients Considered Nonresponders
LVESV	≥15% relative reduction	55% (47/86)	57% (38/67)	47% (9/19)
LVEF	≥5% absolute increase	64% (62/97)	65% (48/74)	61% (14/23)
NYHA class	≥1 class improvement	60% (63/105)	63% (50/80)	52% (13/25)
MR	≥1 class improvement	33% (33/101)	29% (23/78)	43% (10/23)

ALLSYNC=Alternate Site Cardiac Resynchronization; CRT=cardiac resynchronization therapy; LVEF=left ventricular ejection fraction; LVESV=left ventricular end-systolic volume; MR=mitral regurgitation; NYHA=New York Heart Association.

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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].

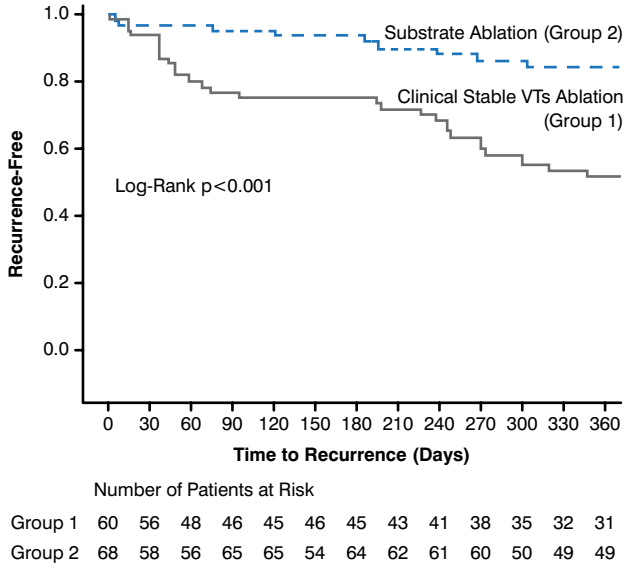
Patients with ischemic cardiomyopathy and stable monomorphic VT may undergo catheter ablation as an option to reduce implantable cardiac defibrillator shocks. However, it is unclear if ablation of the clinical stable VT or more extensive substrate-based ablation is more beneficial. The purpose of the 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 clinical VT ablation and 8% who underwent substrate ablation (p=0.21).

Figure 1. VT Recurrence-Free Survival After Ablation



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