Validation of a defibrillation lead ventricular volume measurement compared to three-dimensional echocardiography

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BACKGROUND There is increasing evidence that using frequent invasive measures of pressure in patients with heart failure results in improved outcomes compared to traditional measures. Admittance, a measure of volume derived from preexisting defibrillation leads, is proposed as a new technique to monitor cardiac hemodynamics in patients with an implantable defibrillator.

OBJECTIVE The purpose of this study was to evaluate the accuracy of a new ventricular volume sensor (VVS, CardioVol) compared with 3-dimenssional echocardiography (echo) in patients with an implantable defibrillator.

METHODS Twenty-two patients referred for generator replacement had their defibrillation lead attached to VVS to determine the level of agreement to a volume measurement standard (echo). Two opposite hemodynamic challenges were sequentially applied to the heart (overdrive pacing and dobutamine administration) to determine whether real changes in hemodynamics could be reliably and repeatedly assessed with VVS. Equivalence of end-diastolic volume (EDV) and stroke volume (SV) determined by both methods was also assessed.

RESULTS EDV and SV were compared using VVS and echo. VVS tracked expected physiologic trends. EDV was modulated −10% by overdrive pacing (14 mL). SV was modulated −13.7% during overdrive pacing (−6 mL) and increased over baseline +14.6% (+8 mL) with dobutamine. VVS and echo mean EDVs were found statistically equivalent, with margin of equivalence 13.8 mL ($P < .05$). Likewise, mean SVs were found statistically equivalent with margin of equivalence 15.8 mL ($P < .05$).

CONCLUSION VVS provides an accurate method for ventricular volume assessment using chronically implanted defibrillator leads and is statistically equivalent to echo determination of mean EDV and SV.

KEYWORDS Admittance; Three-dimensional echocardiography; Ventricular volume sensor; Right ventricular shocking lead; Preload; Left ventricular end-diastolic volume; Heart failure; RECHARGE

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Introduction

The morbidity, mortality, and costs associated with caring for patients with congestive heart failure in the United States is unacceptably high.[1–3] There is a need for cost-effective strategies to prevent expensive hospitalizations before they occur. Recent studies have shown that medication adjustment in response to preload monitoring using implantable pulmonary artery pressure (PAP) monitoring devices reduces morbidity as measured by reduction of hospital readmission.[1] Unfortunately, other approaches to hemodynamic monitoring, including thoracic impedance monitoring, weight monitoring, and left atrial/right ventricular (RV) pressure monitoring, have not improved outcomes.[2]

All implantable sensors carry some adverse event risk and increased cost primarily as a result of the implantation procedure. For this reason, having fewer implantable devices is preferred. A ventricular volume sensor (VVS) could be incorporated into implantable cardioverter–defibrillator

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(ICD) and cardiac resynchronization therapy defibrillator (CRT-D) devices, which are already broadly adopted in patients with reduced ejection fraction (EF) for primary prevention of sudden cardiac death.[3] Heart failure management of those patients could benefit from insight into their hemodynamic status, using the previously implanted leads to measure hemodynamics.

Admittance measurement is a technique that allows for estimation of ventricular chamber volume of the heart in real time in any patient with an implanted RV lead containing shocking coil, ring, and tip connections. Although the concept of measuring impedance to determine blood volume has been present for decades,[4] currently no implanted technology measures phase angle or the imaginary part of admittance, which is a key tissue discrimination tool. From the Frank–Starling relationship, we know that preload is most directly measured by left ventricular end-diastolic volume (LVEDV) because it is dependent on the amount of sarcomere stretch during filling while being less dependent on pulmonic function. Enabled by admittance measurement, VVS can measure LVEDV using existing leads.

Additionally, RV volume changes are an excellent indication of beat-to-beat left ventricular (LV) volume changes in the absence of severe valvular defect.[5] LVEDV measurement using echocardiography (echo) has been proven to have prognostic value for the detection of heart failure,[6] but expense to the patient and resources required from the hospital prevent measurements from being made with sufficiently high frequency to take treatment action.

The purpose of the RECHARGE clinical diagnostic study was to determine whether ambulatory ventricular volume measurement could be made using Admittance on existing RV leads with high reliability and accuracy compared with LV 3-dimensional transthoracic echocardiography (3D echo). This would allow a cost-effective, well-adopted measurement of cardiac preload (EDV) that could be used to reduce morbidity in patients having heart failure with a more direct measure of ventricular preload than obtained from PAP sensors. Additionally, other volume measurements such as stroke volume (SV) could be made to give the clinician insight into changing patient clinical status.

Methods

Patients

All patients referred for clinically indicated replacement of an ICD or CRT-D generator with a chronically implanted RV defibrillation lead were screened for inclusion in the trial. Patients were excluded if they had a history of heart block, pacemaker dependence, and persistent atrial arrhythmia (Figure 1). Patients with integrated bipolar RV leads were excluded because the present VVS system was designed for use with dedicated bipolar RV defibrillator leads. Informed consent was obtained from all patients who fulfilled the inclusion and exclusion criteria. For the purposes of this study, 3D echo was selected as the technology to which admittance measurements would be compared. However, many patients have limited acoustic windows when their body position is supine, as is required during a generator change procedure. Therefore, enrolled patients underwent preprocedural screening with baseline 3D echo analyzed by a core laboratory to determine whether they had acceptable acoustic windows while in a supine position and did not complete the protocol if the screening study was inadequate. The study protocol was approved by the ethics committees of the 6 participating centers. Patient baseline data are summarized in Table 1.

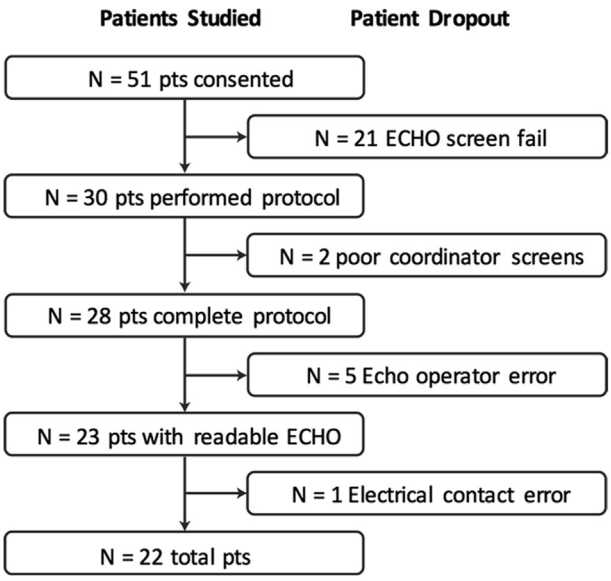

Figure 1 Patient dropout and reasons. Echo screen fails were all adjudicated by the Yale Cardiovascular Research Group (YCRG).

Protocol

Patients were prepped, draped, and sedated per routine clinical practice. The chronic device pocket was incised, and the old device was removed and disconnected from the chronically implanted endocardial leads. The right atrial lead was connected to an external pacemaker to allow pacing of the heart. The RV lead ring, tip, and distal coil electrodes were connected using temporary cables with alligator clips to the VVS electronics off of the sterile field for volume measurement. Because the distal coil is used, VVS measurement can be made with either single- or dual-coil leads. Simultaneous measurements of 3D echo LV chamber volume, including end-diastolic volume (EDV), end-systolic volume (ESV), and SV, were recorded for comparison.

Patient evaluation

A series of 10 evaluation stages were performed as shown in Figure 2. These stages can be logically split into 4 physiologic states. Stage 1 and 8 were used for calibration of the VVS signal (the baseline state). These measurements are not reported in the agreement analysis; their sole purpose was to calibrate VVS to output volumes in milliliters. Stages 2–7 were a series of overdrive pacing interventions designed to reduce EDV and SV, similar to what is commonly done in