Is Dual-Chamber Programming Inferior to Single-Chamber Programming in an Implantable Cardioverter-Defibrillator?
Results of the INTRINSIC RV (Inhibition of Unnecessary RV Pacing With AVSH in ICDs) Study

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Background—The INTRINSIC RV (Inhibition of Unnecessary RV Pacing with AVSH in ICDs) study tested the hypothesis that dual-chamber rate-responsive (DDDR) with atrioventricular search hysteresis (AVSH) 60-130 programming is not inferior to single-chamber (VVI)-40 programming in an implantable cardioverter defibrillator with respect to all-cause mortality and heart failure hospitalizations using an equivalence margin of 5%.

Methods and Results—At 108 centers, 1530 patients with an implantable cardioverter defibrillator indication received a VITALITY AVT (Guidant Corporation, St. Paul, Minn) implantable cardioverter defibrillator programmed consistently to DDDR AVSH 60-130 for the first week. Of those, 988 patients with <20% right ventricular pacing at 1 week were randomized to DDDR AVSH 60-130 or to VVI-40 programming. Among those randomized, 502 were assigned to DDDR AVSH and 486 to VVI. Groups were similar with regard to coronary disease (68%), gender (21% female), and New York Heart Association functional class >I (79%). A total of 32 patients (6.4%) in the DDDR AVSH arm and 46 patients (9.5%) in the VVI arm died or were hospitalized for heart failure during a mean follow-up of 10.4 months (relative risk = 0.67, \( P = 0.072 \) in favor of DDDR AVSH). DDDR AVSH was not inferior to VVI programming (\( P < 0.001 \)). All-cause mortality was not significantly different between the DDDR AVSH arm (3.6%) and the VVI arm (5.1%; \( P = 0.23 \)). The mean percent right ventricular pacing in the DDDR AVSH arm was 10% (median 4%) versus 3% (median 0%) in the VVI arm.

Conclusions—In the INTRINSIC RV trial, among those randomized, DDDR AVSH was associated with similar outcomes as with VVI backup pacing. (Circulation. 2007;115:9-16.)

Key Words: arrhythmia • tachyarrhythmias • defibrillation • electrophysiology • pacing

Data from recent studies have suggested that dual-chamber implantable cardioverter defibrillator (ICD) and pacemaker programming is associated with increased heart failure hospitalizations and total mortality compared with single-chamber (VVI) programming.1-5 These data have led to the belief that dual-chamber pacing in ICDs may worsen or even precipitate heart failure and lead to increased mortality.1 Recently, the Centers for Medicare and Medicaid Services released a decision (CAG-00157R3) stating that providers must justify the medical necessity of implanting any ICD that is not a single-lead/VVI device. To date, no controlled clinical trial supports the safety of dual-chamber pacing in an ICD.

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The DAVID (Dual Chamber and VVI Implantable Defibrillator) trial\(^1\) showed that 1 specific choice of dual-chamber rate-responsive (DDDR) programming parameters leads to worse outcomes than VVI backup pacing, most likely owing to unnecessary right ventricular (RV) pacing. Recent post hoc analyses support these conclusions and highlight the potential adverse consequences of RV pacing.\(^2\) Several randomized trials, however, including those using only pacemakers, suggest potential benefit to dual-chamber programming.\(^2\,\,3\,\,6\,\,9\) Nonrandomized and retrospective pacemaker studies\(^10\) have shown beneficial

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effects with dual-chamber pacing, including improved hemodynamics, especially in patients with heart failure. Dual-chamber ICDs have these and other potential benefits, including enhanced arrhythmia detection and treatment options. Rate-responsive pacing has been demonstrated to improve cardiovascular exercise response in pacemaker patients and heart failure patients receiving cardiac resynchronization therapy. A recent study reported a 38% incidence of chronotropic incompetence in ICD recipients, but the utility of rate-adaptive pacing has not been studied in this population.

DDDR programming has potential to cause harm by several mechanisms other than increasing the risk of unnecessary RV pacing. Right atrial pacing may delay left atrial activation, thereby impairing hemodynamics, especially in cardiac resynchronization therapy candidates. Atrioventricular (AV) interval optimization at rest has not been shown to improve overall outcomes in this population. To date, no clinical study of any ICD population supports the use of a device more complex than an ICD programmed to VVI. The outstanding question arising from this apparently conflicting information is whether patients requiring ICDs benefit from DDRD programming without experiencing any of the subsequent potential negative consequences.

One solution may be to attempt to minimize RV pacing with the AV Search Hysteresis (AVSH) algorithm. AVSH allows intrinsic AV conduction beyond the programmed AV delay. The primary objective of the INTRINSIC RV (Inhibition of Unnecessary RV Pacing with AVSH in ICDs) study was to compare the outcomes (all-cause mortality or heart failure hospitalization) of ICD patients randomized to either DDRD AVSH or VVI programming. It was hypothesized that the rate of death or heart failure hospitalization would be noninferior for patients whose ICDs were programmed to DDRD AVSH compared with those who had ICDs programmed to VVI. (A list of investigators and institutions that participated in the INTRINSIC RV study can be found in the online-only Data Supplement.)

Methods

Study Design

Patients had a standard indication for an ICD and had a VITALITY AVT (Guidant Corporation, St. Paul, Minn) ICD implanted. Informed consent was obtained before enrollment in the trial, and the trial was reviewed by the responsible institutional review boards as applicable. After implantation, patients were programmed to DDRD AVSH 60-130 bpm with a 1-touch programming feature to encourage uniform programming. At the 1-week follow-up visit, the rate of RV pacing was assessed with ICD counters (rates of RV pacing are expressed as percentages of paced beats out of all detected beats). Patients who were RV paced <20% of the time at 1 week were randomized to 1 of 2 standardized programming arms (DDDR AVSH 60-130 or VVI-40) in a 1:1 allocation, stratified by clinical site. Because evidence from the DAVID trial suggested that substantial amounts of RV pacing could pose a safety concern, it was deemed inappropriate to randomize patients who had already shown a propensity for RV pacing when programmed to DDRD. For this reason, the conservative cutoff of 20% RV pacing was chosen. VVI-40 parameters were chosen on the basis of programming in DAVID. In comparison, DDRD AVSH 60-130 was deliberately chosen to provide atrial support pacing and to attempt to limit RV pacing in the presence of intrinsic AV conduction. All patients were scheduled to be seen at 3-, 6-, and 12-month postimplantation follow-up visits. The complete study design and rationale have been described previously.

AV Search Hysteresis

AVSH is a proprietary algorithm that actively searches for intrinsic AV conduction every x cycles (where x is a programmable number from 32 to 1024) and extends the AV delay by 10% to 100% to allow for intrinsic conduction, when present, across the programmed lower to upper rate range. The protocol was revised and AVSH programming parameters were optimized after 313 patients were enrolled (100 randomized) because initially specified AVSH settings resulted in fewer randomized patients than expected. Specifically, 2 settings were modified. Rate hysteresis was set at a 20-bpm offset, which allowed the lower rate limit to approach 40 bpm with intrinsic conduction, and AVSH AV increase % was changed from 50% to 100%. Programming parameters have been described previously.

ICD Programming

A 1-touch programming utility was provided to investigators both for convenience and to help standardize complex programming options. Although investigators were permitted to set additional zones, this feature initially provided tachycardia detection in a single-zone configuration starting at 185 bpm.

Inclusion and Exclusion Criteria

Eligible patients met current ICD indications and completed the informed consent process before implantation at approved centers. Complete inclusion/exclusion criteria are shown in Table 1.

Sample Size

The proportion of VVI patients expected to be event-free at the 12-month follow-up was 93.9%, with a similar rate expected for
those whose ICDs were programmed to DDDR AVSH. Sample size was computed with a noninferiority margin of 5%, with desired power of 80%. The significance level for the primary end point was set at 0.05, 1-tailed.

Under these assumptions, an estimated 420 patients per study arm, or a total of 840 patients, were required to be randomized to provide end-point information. After the protocol amendment, total targeted enrollment was increased to 1500 to account for nonrandomized subjects and patient attrition.

Statistical Analysis
The primary end point in INTRINSIC RV was a composite of all-cause mortality and hospitalization for heart failure. The proportions of patients who experienced an event that qualified for the primary end point were compared between the 2 randomized study arms, and the results were analyzed with Blackwelder’s method to test noninferiority of DDDR AVSH to VVI. Analyses of study outcomes were performed under the intention-to-treat principle, although for the primary end point, a sensitivity analysis with an as-treated assumption was also performed. Additional tests of continuous variables were performed with t tests, and categorical variables were analyzed with chi-squared tests. Statistical tests for noninferiority were 1-tailed, whereas all other tests were 2-tailed. All probability values were deemed significant at a level of 0.05 or below. Statistical analyses were performed with SAS version 9.1 (SAS Institute, Cary, NC).

Data and Safety Monitoring Board
The Data and Safety Monitoring Board, which consisted of 1 electrophysiologist, 1 cardiologist, and 1 statistician independent of the study, and the study sponsor reviewed interim data analysis regularly, including primary and secondary end points. The Data and Safety Monitoring Board was empowered to recommend early termination of the trial; no such cause was found during the conduct of the study.

The authors had full access to the data and take full responsibility for the integrity of the data. All authors have read and agree to the manuscript as written.

Results
Patient Characteristics and Follow-Up
A total of 1530 patients were enrolled over 15 months (ending September 2004) and had an ICD implanted de novo at 1 of the 108 participating clinical sites. Of these, 1461 had their RV pacing assessed at the 1-week visit. At that time, 988 patients were randomized to DDDR AVSH (502 patients) or VVI (486 patients) programming based on RV pacing values below 20%. Therefore, roughly two thirds of enrolled patients qualified for randomization, a figure that increased to 77% when only patients enrolled after the protocol amendment described above are considered.

Patients’ clinical characteristics at baseline were typical of an undifferentiated ICD population. There were no significant differences between the randomized groups at baseline (Table 2). Mean follow-up for randomized patients was 10.4 months. Figure 1 shows the disposition of patients throughout follow-up. Rates of withdrawal and losses to follow-up were comparable between the randomized arms.

A multiple logistic regression with stepwise selection methods was used to model the likelihood of being randomized at the 1-week visit. Higher body mass index (P < 0.001), older age (P < 0.001), male gender (P = 0.002), lower systolic blood pressure at baseline (P = 0.049), and history of atrial fibrillation (P = 0.035) were associated with lower likelihood of randomization, that is, with higher rates of RV pacing at 1 week. Curiously, a history of diabetes mellitus was associated with greater rates of randomization (P = 0.005).

Primary End Point: Heart Failure Hospitalization and All-Cause Mortality
Compared with patients randomized to VVI, those patients randomized to DDDR AVSH experienced 33% fewer deaths and heart failure hospitalizations. Over the course of the study, 32 patients (6.4%) assigned to DDDR AVSH and 46 (9.5%) assigned to VVI experienced an event that met the definition of the primary end point. Statistical analysis of these results demonstrated noninferiority of outcomes in the DDDR AVSH group (P < 0.001), meeting the protocol-defined primary end point. In fact, the DDDR AVSH results trended toward superiority (P = 0.072) compared with VVI. Kaplan-Meier curves illustrating time to death or first heart failure hospitalization are shown in Figure 2. An as-treated analysis on 897 patients for whom the programming mode was consistent over follow-up also showed noninferiority of DDDR AVSH (P < 0.001). There were a total of 91 patients (18%) lost to follow-up in the DDDR AVSH arm and 89 (18%) in the VVI arm. The rates of dropout were similar in both arms, and an examination of causes showed no evidence of differences in the reasons for patients leaving the study. For these reasons, the protocol-defined primary end-point analysis that used proportions of patients experiencing an event would be expected to return statistically valid results. Nevertheless, to account for this censoring, a Cox proportional hazards model22 was also used to analyze the primary end point for both noninferiority and superiority. The noninferiority hypothesis was defined by translating the 5% absolute margin and 9.5% event rate in the control group into a hazard ratio of (0.095 + 0.05)/0.095 = 1.53. The Cox model produced a probability value of 0.001 for noninferiority and 0.063 for superiority of DDDR AVSH compared with VVI. These are both similar to the analysis of proportions.

Additionally, all-cause mortality alone favored the DDDR AVSH arm, with 18 deaths (3.6%) occurring in that group versus 25 (5.1%) in the VVI arm, although that result was not statistically significant (P = 0.23). Kaplan-Meier curves for survival are shown in Figure 3.

Results in the observational arm were less favorable than in either randomized group. Of 473 patients who attended the 1-week visit and were assigned to the observational arm, 59 (12.5%) experienced an event that met the definition of the primary end point, including 26 deaths (5.5%). As previously noted, observational patients tended to be older and more predominantly male than randomized patients, with higher rates of baseline arrhythmias.

Medical Therapy
Medical therapy at 12 months was similar in the randomized groups. Only use of β-blockers differed significantly between the 2 study arms (P = 0.032), with patients randomized to VVI pacing receiving the more aggressive treatment (88.2% ver-
sus 82.4% in the DDDR AVSH group). Medical therapies are displayed in Table 3.

**RV Pacing**

RV pacing in patients randomized to DDDR AVSH indicated a mean of 10% and a median of 4%. By comparison, RV pacing in patients randomized to the VVI group showed a mean of 3% and a median of 0%. Regarding atrial pacing, the mean in the DDDR AVSH group was 13%, with a median of 3%.

**Appropriate Versus Inappropriate Shock**

All episodes for which shocks were delivered and a stored electrogram existed were adjudicated by an independent expert. A total of 375 episodes treated with shock occurred in randomized patients, and rates of inappropriate shock were not significantly different between randomized groups. Sixty-three (48.1%) of 131 episodes were deemed inappropriately treated in the DDDR AVSH arm versus 32 (45.7%) of 70 in the VVI arm. Programming recommendations were the most likely reason for this observation (eg, single-zone detection at 185 bpm). More than half of the INTRINSIC RV population had only a single arrhythmia zone (ventricular fibrillation) programmed, for which heart rate alone was the determinant of therapy. Only 37% had a second (ventricular tachycardia) zone programmed in which detection enhancements were turned on. Of all patients, just 96 (6.3%) of 1530 experienced an inappropriate shock despite monomorphic ventricular tachycardia. This rhythm accounted for 159 (42.4%) of the 375 shocks.

Regardless of device programming, 3-channel electrograms were available for review, and the reviewer was blinded to treatment assignment. A total of 201 episodes treated with shock occurred in randomized patients, and rates of inappropriate shock were not significantly different between randomized groups. Sixty-three (48.1%) of 131 episodes were deemed inappropriately treated in the DDDR AVSH arm versus 32 (45.7%) of 70 in the VVI arm.

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a mean study follow-up of nearly 1 year. The overall incidence of shock, regardless of appropriateness, across randomized groups was analyzed. Patients in the DDDR AVSH arm did not have a statistically significant difference in shock rates compared with the VVI arm ($P = 0.074$).

**Discussion**

The DAVID trial raised concerns over the use of DDDR pacing in ICD recipients. That trial indicated that DDDR programming (especially when RV pacing rates were $>40\%$) was associated with increased heart failure hospitalization and all-cause mortality compared with VVI programming. Other trials have found similar results. These studies led to the notion that DDDR ICDs could harm patients. Although high levels of RV pacing ($>40\%$) are associated with problems such as heart failure hospitalization and all-cause mortality, lower levels may have benefit.

The INTRINSIC RV study represents a diverse patient population with standard ICD indications. Those patients with a DDDR ICD programmed to DDDR AVSH fared as well as or better than those patients with ICDs programmed to VVI. The protocol-specified standardized programming with a 1-touch approach simplified the selection process for device settings, with the goal of reducing RV pacing. Typical RV pacing levels among patients randomized to DDDR programming in INTRINSIC RV were drastically lower than in the DAVID trial (mean of 10\% versus 59\%), which is a likely explanation for the disparity in outcomes of these 2 trials. In fact, DDDR AVSH programming was associated with a trend toward statistical superiority with respect to all-cause mortality and heart failure hospitalization compared with VVI programming.

Dual-chamber ICDs may provide pacing options and increased flexibility in programming compared with VVI devices. For example, they can provide atrial-based pacing support in patients with sinus bradycardia and provide AV synchrony in patients with AV block to potentially ameliorate pacemaker syndrome. Dual-chamber ICDs also...
offer a second electrogram recording channel that may provide more thorough documentation of the rhythm disturbances that cause ICD activation. Recent data suggest that initial implantation of a dual-chamber ICD can save money compared with implantation of a single-chamber device because there may be need for future upgrade of the single-chamber device to a dual-chamber device. Despite these potential benefits, clinically significant advantages of dual-chamber pacing have not been substantiated. Indeed, in the INTRINSIC RV trial, higher rates of both appropriate and inappropriate shocks were found in the DDDR AVSH arm, and the reasons for this are unknown.

In the INTRINSIC RV study, DDDR AVSH did not reduce inappropriate shock rates. INTRINSIC RV was designed to study the effects of pacing algorithms on the clinical outcomes of heart failure hospitalization and all-cause mortality rather than to study how discrimination algorithms for VVI or DDDR programming affected antitachycardia or defibrillation therapies. Because the wide variation in tachyarrhythmia therapy settings could affect end points, for purposes of the present study, 1-touch programming settings limited complex multizone antitachycardia therapies. Our analysis of programming practices indicated that relatively few physicians deviated from the study protocol in favor of more complex programming. Likewise, a minority of physicians activated detection enhancements. Therefore, although DDDR programming might generally be expected to reduce inappropriate shock rates, programming restrictions likely muted any such effect. Patients receiving inappropriate shocks composed 6.3% of all 1530 subjects.

A greater number of patients in the DDDR AVSH arm received shocks than in the VVI arm; this difference was not statistically significant, however, and DDDR AVSH patients fared as well as if not better than their VVI counterparts. Although 1-touch programming settings limited complex multizone antitachycardia therapies, there were no specific requirements regarding tachycardia therapies (ie, antitachycardia pacing, shocks, or combination schemes). These results pose new challenges for further understanding the risks and benefits of dual-chamber ICD programming.

Closer examination of rate-adaptive programming for ICD recipients has been recommended with specific attention to algorithms that reduce RV pacing in concert with rate-adaptive atrial pacing. The INTRINSIC RV study accomplished this goal. Algorithms other than AVSH exist to reduce ventricular pacing in dual-chamber ICDs; however, no other large randomized, prospective study has shown clinical benefits as were shown in the present study. Carefully controlled clinical trials will be required to show any advantage of a specific programming approach. Indeed, the INTRINSIC RV study is the first to determine whether an algorithm that reduced RV pacing could limit the adverse effects of RV pacing yet preserve the benefits of a dual-chamber ICD.

**Study Limitations**

This study was designed with minimal enrollment restrictions. Because more specific indications were not required, variables such as ejection fraction were not collected.

The definition of excessive RV pacing as >20% may have been too conservative, because RV pacing rates as high as 40% may not necessarily incur adverse consequences. Because of this criterion, approximately one third of enrolled patients did not qualify for randomization despite a protocol amendment to adjust programming parameters that ultimately reduced the rate of nonrandomization to less than one quarter.

Investigators and patients were not blinded to randomization assignment. Despite this, examination of follow-up

### TABLE 3. Medical Therapy at 12 Months

<table>
<thead>
<tr>
<th>Medication</th>
<th>DDDR AVSH (n=393)</th>
<th>VVI (n=372)</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>β-Blockers</td>
<td>324 (82.4)</td>
<td>328 (88.2)</td>
<td>0.032</td>
</tr>
<tr>
<td>Angiotensin-converting enzyme inhibitors</td>
<td>274 (69.7)</td>
<td>243 (65.3)</td>
<td>0.22</td>
</tr>
<tr>
<td>Angiotensin II receptor blockers</td>
<td>57 (14.5)</td>
<td>45 (12.1)</td>
<td>0.34</td>
</tr>
<tr>
<td>Diuretics</td>
<td>209 (53.2)</td>
<td>211 (56.7)</td>
<td>0.35</td>
</tr>
<tr>
<td>Spironolactone</td>
<td>51 (13.0)</td>
<td>49 (13.2)</td>
<td>1.00</td>
</tr>
<tr>
<td>Calcium channel blockers</td>
<td>42 (10.7)</td>
<td>39 (10.5)</td>
<td>1.00</td>
</tr>
<tr>
<td>Amiodarone</td>
<td>39 (9.9)</td>
<td>26 (7.0)</td>
<td>0.16</td>
</tr>
</tbody>
</table>

Values are n (%).
data indicated that patients were treated similarly in both randomized groups.

Finally, complex DDDR AVSH programming may appear to be a challenge, but for the convenience of the investigator, this was simplified with use of a 1-touch programming technique.

**Conclusion**

Among ICD recipients randomized in the INTRINSIC RV trial, DDDR AVSH was not inferior to VVI backup programming with regard to all-cause mortality and heart failure hospitalization. A trend toward lower rates of mortality and heart failure hospitalization in the DDDR AVSH arm was observed but was not statistically significant. The present study is the first in an ICD population to show that DDDR programming can be as good as if not better than VVI programming.

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**Disclosures**

Dr Olshansky serves on the speakers bureau of Boston Scientific CRM, has received honoraria from Boston Scientific CRM, and is a consultant/advisory board member of Boston Scientific CRM. Dr Gering has received honoraria from Boston Scientific CRM, Medtronic, and Biotronik. Dr McGuire has ownership interest in Boston Scientific CRM and is employed by Boston Scientific CRM. Dr Brown is an employee of Integra Clinical Trial Solutions, which is a subsidiary of Boston Scientific CRM. Dr Gering has received honoraria from Boston Scientific CRM, and is employed by Boston Scientific CRM. Dr Gering has received honoraria from Boston Scientific CRM, and is a consultant to Medtronic and Boston Scientific CRM. Dr Brown is an employee of Boston Scientific CRM and is employed by Boston Scientific CRM.

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Clinical Perspective

Dual-chamber (DDDR) implantable cardioverter defibrillators are often the preferred device for patients undergoing implantable cardioverter defibrillator implantation, but some data suggest that compared with single-chamber programming, DDDR programming is associated with an increased risk of heart failure hospitalization and total mortality. We hypothesized that this risk was not due to DDDR programming per se but rather to excessive right ventricular pacing. The INTRINSIC RV (Inhibition of Unnecessary RV Pacing with AVSH in ICDs) study showed in a broad implantable cardioverter defibrillator population that DDDR programming, with atrioventricular search hysteresis to limit excessive right ventricular pacing yet preserve atrioventricular synchrony, resulted in outcomes as good as, if not better than, single-chamber programming. DDDR implantable cardioverter defibrillators programmed to DDDR with atrioventricular search hysteresis should be considered for patients who may benefit from DDDR programming.

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