Implantable Atrial Defibrillator With a Single-Pass Dual-Electrode Lead

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OBJECTIVES

We examined the feasibility and efficacy of using a single-pass, dual-electrode (Solo) lead for atrial fibrillation (AF) detection and defibrillation.

BACKGROUND

The efficacy and safety of an implantable atrial defibrillator (IAD) has been extensively studied; however, separate right atrial (RA) and coronary sinus (CS) defibrillation leads are used for the present system.

METHODS

We studied the use of the Solo lead for AF detection and defibrillation in 17 patients who underwent cardioversion of chronic AF. The Solo lead with a proximal 6-cm RA electrode and a distal 6-cm spiral-shaped CS electrode were positioned into the CS with the RA electrode against the anterolateral RA wall. The RA-CS electrogram signal amplitudes were measured and the efficacy of the Solo lead for AF detection and defibrillation was assessed by using an external version of the IAD.

RESULTS

The leads were inserted in all patients without complication (mean fluoroscopy time: 13.3 ± 6.8 min). The mean RA-CS signal amplitude was 484 ± 229 μV during sinus rhythm and 274 ± 88 μV during AF (p < 0.05). All patients had satisfactory atrial signal amplitude to allow accurate detection of sinus rhythm. Successful cardioversion was achieved in 16/17 (94%) patients with an atrial defibrillation threshold of 320 ± 70 V (5.5 ± 2.7 J). Insufficient interelectrode spacing resulted in suboptimal electrode locations, associated with a lower atrial signal amplitude, a higher atrial defibrillation threshold and diaphragmatic stimulation.

CONCLUSIONS

These results suggest a simplified lead configuration with optimal interelectrode spacing can be used with an IAD for AF detection and defibrillation. (J Am Coll Cardiol 1999;33: 1974–80) © 1999 by the American College of Cardiology

Recent studies of animals (1) and humans (2–7) have shown that low energy, biatrial, R-wave synchronized shocks delivered transvenously are safe and effective for cardioversion of atrial fibrillation (AF). These findings prompted the development of an implantable atrial defibrillator (IAD) as a new therapeutic prospect for patients with drug refractory AF (8,9). To minimize atrial defibrillation threshold, with its implication on battery longevity and patient tolerability, electrodes should be positioned so that they encompass both atria. Previous studies show that this is best achieved with one electrode in the right atrium (RA) and one in the distal coronary sinus (CS) (1,3,10). However, a disadvantage of the currently available lead system is the need for separate RA and CS leads. The need for multiple leads increases the cost, time of the implantation procedure and potential risks of perioperative and late complications. The development of a single-pass lead with both the RA and CS defibrillation electrodes on the same lead would simplify the implantation of an IAD. The aims of this study were to investigate the following: 1) the feasibility and efficacy of using a single-pass, dual-electrode defibrillation lead for AF detection and defibrillation; 2) the effects of different electrode locations resulting from different interelectrode spacing on AF detection and defibrillation, and 3) the lead stability and changes in atrial signal amplitude during changes in patient posture.

METHODS

Study population. All patients gave written informed consent before the procedure, and the study protocol was approved by the local ethics committee. Transvenous atrial defibrillation was performed in 17 patients (15 males, two female; mean age 61 ± 10 years, range 34 to 76) with electrocardiographically documented persistent AF (mean duration of AF, 24 ± 16 months, range: 7 to 60 months). After detailed medical history and physical examination, all patients underwent a preprocedure evaluation consisting of a 12-lead electrocardiogram, 24-h Holter monitoring, chest X ray, transthoracic and transesophageal echocardiography.
and routine laboratory and thyroid function tests. Patients with the following conditions were excluded from this study: 1) reversible causes of atrial fibrillation, such as electrolyte imbalance and hyperthyroidism; 2) clinically significant valvular heart disease; 3) unstable angina or recent myocardial infarction within the past 6 months; 4) New York Heart Association class III or IV heart failure, and 5) echocardiographic evidence of left atrial thrombi.

Underlying heart disease was present in 12 (71%) patients, including hypertension (n = 9), thyroid heart disease (n = 1), dilated cardiomyopathy (n = 1) and mild mitral valvular heart disease (n = 1). Their mean left ventricular ejection fraction and left atrial diameter was 61 ± 10% and 4.68 ± 0.82 cm, respectively. All patients were treated with oral amiodarone and with oral anticoagulation using warfarin to achieve an international normalized ratio of 2–3 for at least 3 weeks before the procedure.

Defibrillation lead placement. Patients were brought to the cardiac electrophysiology laboratory in the postabsorptive, nonsedated state. Local anesthesia at the sites used for catheter insertion was achieved by subcutaneous infiltration of bupivacaine (0.25%). An 11-F and a 7-F sheath were introduced into the left subclavian vein using two separate venapunctures. A custom-made single-pass passive fixation implantable defibrillation lead (Perimeter Solo Model 7305, 7309 or 7312, InControl, Redmond, Washington) was used for testing. The overall length of the lead was either 75 cm or 85 cm with a maximal diameter of 3.3 mm. This lead had two elongated coil electrodes used for atrial fibrillation detection and defibrillation. The proximal (RA) and distal (CS) electrodes had a defibrillation coil electrode length of 6 cm and an electrode surface area of 7.1 cm² and 4.5 cm², respectively. The distal defibrillation coil forms a pigtail-like spring coil of 2.5 turns when the stylet is withdrawn (Fig. 1). Leads with different interelectrode spacing (5 cm, 9 cm and 12 cm) were chosen at random and tested in different patients. For defibrillation shock delivery, the RA electrode served as the cathode and the CS electrode as the anode with respect to the first phase of the shock.

With the use of a stiff stylet shaped with a gentle curve, the lead was advanced into the CS under fluoroscopic guidance. The lead was positioned to have the distal electrode in the distal CS with the proximal electrodes against the anterolateral RA wall whenever possible. A ventricular passive fixation pacing lead (Model 4024, Medtronic, Minneapolis, Minnesota) was placed in the right ventricular apex for R-wave synchronization and postshock pacing.

The IAD. The METRIX Defibrillation System Analyzer (Model 2101 or 2102, InControl, Redmond, Washington) was connected to the leads and was used to simulate the functionality of the Metrix IAD. The device monitors the intracardiac atrial (RA-CS vector) and ventricular (RV bipolar) electrogram using specific AF detection and R-wave synchronization algorithm, for AF detection and for synchronized shock delivery. The details of these algorithms of the IAD have been described previously (10–12).

After successful AF detection and R-wave synchronization, R-wave synchronized biphasic shock of 3/3 ms (Model 2101) or 6/6 ms (Model 2102) can be delivered at selected voltages, with a maximal intensity of 400 V.

Study protocol. Testing was performed after the patients were sedated with intravenous midazolam (0.05 mg/kg) and

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**Abbreviations and Acronyms**

AF = atrial fibrillation  
CS = coronary sinus  
IAD = implantable atrial defibrillator  
RA = right atrium

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**Figure 1.** Single-pass, dual-electrode implantable (Solo) lead used for transvenous atrial defibrillation. Note the spring coil of the coronary sinus electrode after the stylet is withdrawn (bottom).
pethidine (0.5 mg/kg), and additional doses were given as required. The AF detection algorithm of the IAD was tested, and data, including the electrogram, were stored for analysis of the electrogram signal amplitude. Furthermore, in seven patients, the RA-CS electrograms were evaluated using the AF detection algorithm during AF and sinus rhythm while the patient assumed both a supine and upright posture. All stored RA-CS electrograms were evaluated after signal processing using a filter setting of 40 to 500 Hz for the determination of the mean atrial signal amplitude during AF and sinus rhythm.

After running the AF detection algorithm, a test shock of 20 V was delivered to assess the integrity of the defibrillation system and to test the synchronization process. R-wave synchronized, biphasic shocks (3/3 ms or 6/6 ms waveform) were delivered for cardioversion, starting with a shock intensity of 180 V. The shock intensity was increased in steps of 40 V until sinus rhythm was restored (atrial defibrillation limit) or until a shock of the maximal intensity deliverable from the device (400 V) was reached. The shock with the lowest intensity that resulted in successful conversion was considered the defibrillation threshold. After successful cardioversion, patients were then placed onto a tile table and the stability of the lead position was assessed by fluoroscopy during supine and upright (70° tilting for 5 min) posture. At the end of the procedure, both the Solo lead and the RV pacing lead were removed from all patients.

**Statistical analysis.** Results are expressed as mean ± SD. Statistical differences were analyzed with Fisher exact test for categorical variables and Mann-Whitney $U$ test for continuous variables. Multiple comparisons between the atrial signal amplitude at different electrode locations during AF and sinus rhythm were performed using two-way repeated measures analysis of variance, followed by Bonferroni $t$ tests for individual comparisons. A value of $p < 0.05$ was considered statistically significant.

**RESULTS**

**Lead placement and electrode locations.** The leads were inserted in all patients through the left subclavian vein without complication. The mean fluoroscopy time necessary for lead placement was $13.3 ± 6.8$ min (range: 7 to 22.5 min). The final position of the defibrillation electrodes was related to the interelectrode spacing of the lead used, and these data are shown in Table 1. When a lead with 5-cm interelectrode spacing was used, the position of the RA and CS electrodes in those patients was in the low anterolateral RA and mid-CS, respectively (Fig. 2A). The short interelectrode spacing between the two electrodes prevented the CS electrode from being advanced into the distal CS, as this would have resulted in the RA electrode being positioned at or inside the ostium of the coronary sinus. On the other hand, when a lead with a longer interelectrode spacing (9 or 12 cm) was used, the position of

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<th>LA Size (cm)</th>
<th>IES (cm)</th>
<th>Electrode Location</th>
<th>Waveform (ms)</th>
<th>ADFL (V)</th>
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ADFL = atrial defibrillation limit; AF = atrial fibrillation; CS = coronary sinus; DCS = distal coronary sinus; IES = interelectrode spacing; LA = left atrium; LRA = low anterolateral right atrium; MCS = mid-coronary sinus; MRA = midanterolateral right atrium; RA = right atrium; SR = sinus rhythm.
the RA and CS electrodes in most patients (all but two) were in the mid anterolateral RA and distal CS (Fig. 2B).

**Atrial signals for AF detection.** The mean RA-CS signal amplitude during sinus rhythm was significantly greater than that of AF ($484 \pm 229 \mu V$ vs. $274 \pm 88 \mu V$, $p < 0.001$). Atrial fibrillation detection testing with the IAD was performed 313 times. During sinus rhythm, 119 tests of AF detection were performed and accurate identification of sinus rhythm was always achieved (0% false positive rate). During AF, 194 tests of AF detection were performed, and there were 43 episodes (22%) of incomplete AF detection in six patients due to low RA-CS signal amplitude. All of these patients had successful AF detection after repeated testing or after reprogramming the gain setting. For the 151 tests during AF, all episodes were detected approximately (100% true positive rate). Overall, the atrial signal from the RA and CS electrodes of the Solo lead had sufficient amplitudes for AF detection by the IAD during sinus rhythm and AF.

**Transvenous atrial defibrillation.** R-wave synchronization was accurate in all the patients studied. Successful cardioversion was achieved in 16 of the 17 patients (94%). A total of 142 shocks were delivered ($6.8 \pm 3.6$ shocks/patient) during the procedure. The mean atrial defibrillation threshold was $320 \pm 70 \text{V}$ with a corresponding energy of $5.5 \pm 2.7 \text{J}$. The mean shock impedance was $67 \pm 9 \Omega$. The procedure did not induce ventricular arrhythmia nor result in other complications.

**Effects of electrodes location.** The efficacy of the Solo lead for atrial sensing and defibrillation at low anterolateral RA–mid-CS electrodes location (group 1) was compared with that at mid anterolateral RA–distal CS (group 2) (Table 2). There were no significant differences between the two groups regarding their clinical characteristics, successful rate of cardioversion and the percentage ratio of the two biphasic shock waveforms (3/3 ms and 6/6 ms) used. However, patients in group 1 had significantly lower atrial signal amplitudes during both AF and sinus rhythm (Fig. 3A) and significantly higher atrial defibrillation thresholds as compared with patients in group 2. With respect to signal amplitudes, there was a significant interaction between electrode location and rhythm ($p < 0.05$), denoting that the signal amplitude changes associated with rhythm (AF vs. SR) were greater for group 2 (mid anterolateral RA–distal CS). The shock impedance was also significantly lower in group 1 as compared with group 2. Furthermore, four of eight patients (50%) in group 1 experienced clinically significant diaphragmatic stimulation during shock delivery. All of them started to have diaphragmatic stimulation at the lowest energy of the defibrillation shock (i.e., 180 V). Thus, the presence of the diaphragmatic stimulation was independent of the strength of the shock. In contrast, none of the patients in group 2 had diaphragmatic stimulation during defibrillation at any intensity of shock delivered.

**Effects of changes in posture.** In all patients, fluoroscopic examination of the lead location during changes in posture from supine to upright revealed no significant changes in lead location nor any lead dislodgments. There was no significant differences in the RA-CS signal amplitudes comparing supine and upright postures during both AF and sinus rhythm (Fig. 3B). There was a significant interaction between posture and rhythm ($p < 0.05$) that can be visualized on the graph: supine posture is associated with a
slightly lower signal amplitude than the upright posture during AF that reverses during sinus rhythm.

**DISCUSSION**

**Main findings.** The results of the present study have demonstrated the feasibility and efficacy of using an implantable single-pass, dual-electrode lead for both AF detection and defibrillation with an IAD. The atrial signals from the RA-CS vector with this lead were of sufficient amplitude for accurate AF detection. Successful cardioversion of AF by the Solo lead was achieved in 94% of patients with persistent AF with average threshold of 320 V, 5.5 J. There were no clinically significant changes in the lead location nor in the atrial signal amplitudes observed during change in patient posture. Furthermore, the electrode location of the Solo lead has a significant effect on its efficacy in detection and defibrillation of AF; the electrodes should be positioned to the mid anterolateral RA and distal CS by using a lead with optimal interelectrode spacing.

**Detection of AF.** Location and configuration of the atrial sensing electrodes are important determinants of the signal characteristics during AF as compared with a more organized rhythm (13), due to the smaller signal amplitude during AF (14). Furthermore, as the atria are activated randomly with multiple simultaneous wavelets, signals recorded from a widely spaced bipole tend to appear more “fibrillatory,” with a faster rate and more fractionation as compared with those from a closely spaced bipole. Thus, using a large surface area, widely spaced electrodes that are capable of capturing atrial signals from multiple sites may have an advantage for certain algorithms used to detect AF. Previous studies (9–11) have demonstrated sufficient atrial signal amplitudes for accurate AF detection can be achieved using the RA-CS sensing vector recorded from large surface area electrodes in the RA and CS.

Our results demonstrated that the atrial signals recorded from the “floating” RA electrode and a distal CS electrode on the Solo lead were of sufficient amplitude to allow accurate detection of AF and sinus rhythm by the IAD. Consistent with the results of a previous study (14), we found that the atrial signal amplitude was significantly lower during AF as compared with sinus rhythm. Changes in

**Table 2.** Comparison Between the Two Electrode Locations

<table>
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<th>Electrode Location</th>
<th>Low RA–Mid-CS (Group 1)</th>
<th>Mid-RA–Distal CS (Group 2)</th>
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<td>8</td>
<td></td>
</tr>
<tr>
<td>Age (yr)</td>
<td>61 ± 13</td>
<td>60 ± 6</td>
<td>0.481</td>
</tr>
<tr>
<td>AF duration (mo)</td>
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<td>21 ± 15</td>
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<tr>
<td>Left atrial size (cm)</td>
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<td>4.70 ± 1.02</td>
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<tr>
<td>Ejection fraction (%)</td>
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<td>57 ± 16</td>
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</tr>
<tr>
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<td>2:6</td>
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<td>368 ± 44</td>
<td>278 ± 63</td>
<td>0.005*</td>
</tr>
<tr>
<td>Energy (J)</td>
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<td>4.18 ± 1.57</td>
<td>0.036*</td>
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<tr>
<td>Impedance (Ω)</td>
<td>62 ± 6</td>
<td>71 ± 10</td>
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<td>RA-CS amplitude (μV):</td>
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<tr>
<td>AF</td>
<td>218 ± 67</td>
<td>323 ± 74</td>
<td>0.008*</td>
</tr>
<tr>
<td>SR</td>
<td>336 ± 110</td>
<td>675 ± 231</td>
<td>0.011*</td>
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</table>

*p values < 0.05.
ADFT = atrial defibrillation threshold; AF = atrial fibrillation; CS = coronary sinus; RA = right atrium; SR = sinus rhythm.

Figure 3. Atrial signal amplitude detected by the Solo lead in right atrial (RA) to coronary sinus (CS) vector during sinus rhythm (SR) and atrial fibrillation (AF). (A) Comparison of the atrial signal amplitudes between different electrode locations. *p < 0.05. **Solid bar** = all; **open bar** = LRA-MCS; **striped bar** = MRA-DCS. (B) Comparison of the atrial signal amplitude during supine and upright posture. *p < 0.05. **Solid bar** = supine; **open bar** = upright. DCS = distal coronary sinus; LRA = mid-right atrium; MCS = midcoronary sinus; MRA = mid-right atrium.
atrial signal amplitude associated with different postures is an important consideration when using a lead with a floating atrial electrode for AF detection. A large inter- and intraindividual variability of the atrial signal amplitude when using a floating atrial electrode has been observed during different postures and movements with other lead systems (15,16). Our results have demonstrated that the preformed spiral shape in the distal CS electrode of the Solo lead has enhanced the stability of the electrodes both in the CS and in the RA. In this study, no significant changes in lead location nor in atrial signal amplitudes were observed with changes in body posture.

More important, we observed that the locations of the electrodes also have a significant impact on the sensed atrial signal amplitude. The signal amplitude recorded using the mid anterolateral RA–distal CS vector was significantly larger than those recorded using the low anterolateral RA–mid-CS vector during atrial fibrillation and sinus rhythm. There are several possible explanations for this finding. First, a wider signal detection vector between mid anterolateral RA–distal CS as compared with the low RA–mid anterolateral CS may increase the signal amplitude by encompassing more of the atria, therefore sensing more of the global signal from the atria. Second, the atrial signals from low anterolateral RA–mid-CS vector may be more contaminated by a large ventricular component, and some of the atrial signals may be lost during blanking of the ventricular signal. Because the ventricular signal was blanked by the algorithm from which data were saved, we were unable to test this hypothesis. Finally, there may exist regional differences in the atrial signal amplitude within the RA accounting for the differences due to far field versus near field sensing. Previous studies have demonstrated that the mid-RA is usually the best location for sensing atrial signals when using floating atrial electrodes (17,18).

Transvenous atrial defibrillation. The successful application of transvenous shock using a biphasic waveform and a RA to CS shock vector for atrial defibrillation have led to the development of an IAD for treatment of recurrent AF (8,9). However, a disadvantage of the currently available system is the need for a separate RA and CS lead to achieve a satisfactory atrial defibrillation threshold, with implications for device battery longevity and patient tolerability (1,3,10). The need for multiple lead placements may increase the implantation procedure time, which may increase the risk of perioperative complications. In addition, the presence of more leads may increase the risk of late complications such as lead dislodgments. Recent studies have demonstrated a similar atrial defibrillation threshold when comparing a temporary, single-pass transvenous catheter and separate RA and CS catheters used for internal cardioversion of atrial fibrillation (19–21), but the stability and feasibility of a lead for permanent use remained uncertain. Our results have confirmed the efficacy of a single-pass lead for atrial defibrillation when used with an IAD. Using the Solo lead, successful cardioversion was achieved in up to 94% of patients with a comparable atrial defibrillation threshold and energy requirement as reported in previous studies using conventional two-lead configuration (2–7). We were also able to show the implant feasibility and electrode/lead stability during changes in posture of this implantable grade, single-pass lead for AF detection and atrial defibrillation.

Consistent with a recent study (10), we found the locations of the defibrillation electrodes have a significant effect on the efficacy of atrial defibrillation. Insufficient interelectrode spacing of the Solo lead resulted in suboptimal electrode locations, with the electrodes positioned to low RA and mid-CS. These electrode locations associated with this insufficient interelectrode spacing were associated with a lower atrial sensing signal amplitude and a higher defibrillation threshold and caused shock intensity–independent diaphragmatic stimulation in up to 50% of patients. The effect of interelectrode spacing on atrial signal amplitude has been discussed previously. Similar to the amplitude changes, the higher defibrillation threshold was also probably due to having a smaller amount of fibrillating tissue encompassed by the low anterolateral RA–mid-CS vector compared with the mid anterolateral RA–distal CS vector (1). In addition, the shorter distance between the electrodes causes a lower shock impedance, probably due to shunting of current through the blood resulting in fewer areas of the atria reaching an adequate potential gradient to achieve defibrillation. Last, it seems likely that a higher local potential gradient in the posterior aspect of the heart due to the location of the electrodes is the cause of the diaphragmatic stimulation. Thus, the interelectrode spacing of the Solo lead should be adjusted in a given patient so that the electrodes are positioned in the mid anterolateral RA and in the distal CS to achieve optimal AF detection and lowest atrial defibrillation thresholds and to avoid diaphragmatic stimulation.

Conclusions. A simplified lead configuration, comprising a single-pass, dual-electrode atrial defibrillation lead and a standard RV pacing lead, can be used with an implantable atrial defibrillator. This new lead system is effective for both atrial fibrillation detection and atrial defibrillation. The defibrillation electrodes on the single-pass lead should be positioned in the mid-RA and distal CS by using a lead with optimal interelectrode spacing, thereby achieving optimal atrial sensing and defibrillation thresholds, without causing diaphragmatic stimulation.

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