Initial Clinical Experience With Ambulatory Use of an Implantable Atrial Defibrillator for Conversion of Atrial Fibrillation

Emile G. Daoud, MD; Carl Timmermans, MD; Chris Fellows, MD; Robert Hoyt, MD; Robert Lemery, MD; Kathy Dawson, PhD; Gregory M. Ayers, MD, PhD; for the Metrix Investigators

Background—A recent study has shown that the implantable atrial defibrillator can restore sinus rhythm in patients with recurrent atrial fibrillation when therapy was delivered under physician observation. The objective of this study was to evaluate the safety and efficacy of ambulatory use of the implantable atrial defibrillator.

Methods and Results—An atrial defibrillator was implanted in 105 patients (75 men; mean age, 59 ± 12 years) with recurrent, symptomatic, drug-refractory atrial fibrillation. After successful 3-month testing, patients could transition to ambulatory delivery of shock therapy. Patients completed questionnaires regarding shock therapy discomfort and therapy satisfaction using a 10-point visual-analog scale (1 represented “not at all,” 10 represented “extremely”) after each treated episode of atrial fibrillation. During a mean follow-up of 11.7 months, 48 of 105 patients satisfied criteria for transition and received therapy for 275 episodes of atrial fibrillation. Overall shock therapy efficacy was 90% with 1.6 ± 1.2 shocks delivered per episode (median, 1). Patients rated shock discomfort as 5.2 ± 2.4 for successful therapy and 4.2 ± 2.2 for unsuccessful therapy (P ≤ 0.05). The satisfaction score was higher for successful versus unsuccessful therapy (3.4 ± 3.3 versus 8.7 ± 1.3; P < 0.05). There was no ventricular proarrhythmia observed throughout the course of this study.

Conclusions—Ambulatory use of an implantable atrial defibrillator can safely and successfully convert most episodes of atrial fibrillation, often requiring only a single shock. Successful therapy is associated with high satisfaction and only moderate discomfort. (Circulation. 2000;102:1407-1413.)

Key Words: defibrillation ■ shock ■ cardioversion ■ outpatient therapy

Electrical cardioversion is an established technique for restoration of sinus rhythm in patients with atrial fibrillation. Defibrillation with transvenous catheter-based electrodes has been shown to be safe and effective for restoration of sinus rhythm, even in patients who have failed attempts to restore sinus rhythm with transthoracic shocks. From this experience, an implanted atrial defibrillator was developed to treat patients with recurrent, symptomatic, drug-refractory atrial fibrillation. Previous studies have reported accurate device detection and safe cardioversion of symptomatic atrial fibrillation; however, device activation and therapy delivery were performed in the hospital under the direction of a physician. The purpose of this study was to evaluate the ambulatory use of the atrial defibrillator. In particular, this study assessed the ability of the implantable atrial defibrillator to accurately detect and safely cardiovert clinical episodes of atrial fibrillation and assessed patient acceptance of therapy when delivered in the outpatient setting.

Methods

Patient Population
The atrial defibrillator was implanted in 105 patients with recurrent, symptomatic, drug-refractory atrial fibrillation. The patients enrolled in this study had substantial contact with the healthcare system, with most patients requiring several emergency room visits or hospitalizations for management of atrial fibrillation (Table 1). All patients provided written informed consent, and the protocol was approved by the hospital institutional review board or ethics committee. Inclusion and exclusion criteria were previously described. Concomitant pharmacological treatment was documented; however, the choice of and alteration in drug therapy were under the direction of the physician.

Atrial Defibrillator
An atrial defibrillator (Metrix models 3000 and 3020, InControl/Guidant, Inc) was implanted in conjunction with 2 defibrillation leads and a bipolar pacemaker lead. The leads were introduced through the subclavian vein, and the defibrillation leads were positioned in the right atrium (InControl/Guidant model 7205) and...
distal coronary sinus (InControl/Guidant model 7109). The pace-
maker lead was placed in the right ventricle (Figure 1). The earlier
atrial defibrillator generator (model 3000) had a maximum output of
300 V (≈3 J). The next-generation device (model 3020) also had a
maximum output of 300 V, but with a larger capacitor, the maximum
delivered energy was ≈6 J. Each model delivers a biphasic wave-
form shock. The defibrillator could be programmed to provide ≈8
shocks, with individual voltages programmable from 20 to 300 V in
10-V increments. The device uses a dual algorithm to detect atrial
fibrillation, and defibrillation shocks are synchronized to the R
wave.6 The device also manages postshock bradycardia with VVI
pacing.

The atrial defibrillator can be programmed to 1 of 5 operating
modalities: automatic, patient-activated, monitor, pacing-only, or off
mode. In the automatic mode, the device is programmed, from every
minute to 120 minutes, to monitor the cardiac rhythm for the
presence of atrial fibrillation. Therapy will be delivered if atrial
fibrillation is present unless the patient inhibits device therapy with
a conventional pacemaker magnet. The patient-activated mode
allows the patient to activate the device with a pacemaker magnet. If
the device detects atrial fibrillation, therapy will be delivered unless
inhibited by a magnet. The monitor mode functions like the auto-
matic mode with respect to atrial fibrillation detection; however, the
device does not deliver defibrillation therapy. For the modes in
which therapy is delivered, a warning shock (10 to 20 V) can be
programmed to discharge before delivery of the therapeutic shock.
When programmed to the pacing-only mode, the device paces in a
VVI mode.

The device stores 3 electrograms for each episode of atrial
fibrillation. The atrial fibrillation detection electrogram displays 3
seconds of atrial and ventricular signals. The second electrogram
displays the ventricular electrogram recorded for 3 seconds before
the delivery of shock therapy. In this electrogram, a mark is placed
on the R wave to which shock therapy was synchronized. The third
electrogram displays atrial and ventricular signals for 4 seconds
after the shock (Figure 2). These electrograms were reviewed to assess the
accuracy of device-based atrial fibrillation detection,6 to confirm
synchronization, to evaluate the outcome of shock therapy, and to
detect ventricular proarrhythmia. Ventricular proarrhythmia was
defined as ≥3 consecutive ventricular beats at a cycle length
<600 ms.

**Postimplantation Follow-Up**

For at least the first 3 months after implant, the atrial defibrillator
was programmed to the monitor mode, and patients were instructed
to return to the hospital or clinic for outpatient treatment of each
symptomatic episode of atrial fibrillation. Defibrillation was then
performed under physician observation during ECG recording.
These therapies are reported as outpatient defibrillator therapy. After
≥3 months of follow-up, the following criteria were required to
transition from outpatient defibrillator therapy to ambulatory device

![Figure 1. Anterior-posterior (A) and lateral (B) chest radiograph of atrial defibrillator. There are 3 leads: 1 defibrillation lead in distal coronary sinus, 1 defibrillation lead in right atrium, and 1 bipolar lead in right ventricle. Pulse generator is in left pectoral region.](image-url)
therapy: an atrial defibrillation energy requirement of 2.60 V (2.6 J for the 3000 model and 5.4 J for the 3020 model); no false-positive detection of atrial fibrillation; correct R-wave synchronization; patient education regarding device activation/deactivation; and 1 episode of atrial fibrillation treated with outpatient defibrillator therapy under physician observation fulfilling each of the following requirements: successful termination with 300 V, therapy delivered during similar conditions as for ambulatory use, patient acceptance of therapy, and sinus rhythm maintained for 1 week after therapy.

After transition to ambulatory therapy, the device was programmed to the patient-activated or the automatic mode. Mode selection was left to the discretion of the physician in conference with the patient. Anxiolytics and/or narcotics were rarely prescribed.

The patient was instructed to complete an event form and to return for clinical follow-up after each treated episode of atrial fibrillation. The event form recorded the patient-perceived onset of symptoms and assessed the patient’s perception of atrial fibrillation and device therapy. A visual-analog scale (1 represented “not at all,” 10 represented “extremely”) was used to score the answers to the following questions: “How severe were the symptoms from this episode of atrial fibrillation?” “How satisfied were you with the therapy?” “How uncomfortable was the therapy?” The fourth question required a yes/no response to, “Did device therapy relieve symptoms?”

Using the stored electrograms and the patient’s report of symptoms, the investigator determined whether an individual episode of atrial fibrillation was terminated. Ambulatory efficacy was defined as the percentage of episodes terminated by the device when treated away from the hospital/clinic. Therapy efficacy was defined as the overall percentage of episodes converted by the atrial defibrillator to stable sinus rhythm either with treatment delivered while the patient was ambulatory or when the patient was treated in the hospital/clinic.

**Statistical Analysis**

Continuous variables are expressed as mean±SD and were compared by use of an ANOVA. Population safety and efficacy calculations were made by fitting the distributions of these variables in an individual patient (assuming a exponential distribution for risk of proarrhythmia and a binomial probability distribution for efficacy) and then determining the mean across the population of patients, assuming a β distribution. Similarly, the risk of proarrhythmia was calculated for the patient population. For all analyses, P<0.05 conferred statistical significance.

**Results**

**Patient Characteristics**

Patient characteristics are summarized in Table 2, and antiarrhythmic therapy at time of last follow-up is summarized in Table 3. Structural heart disease was present in 78 patients (74%), and patients failed 4.8±2.1 antiarrhythmic drugs. Antiplatelet therapy or anticoagulation was prescribed at the discretion of the investigator. There were no thromboembolic events.

Of the 105 patients enrolled, the device was explanted in 15 patients. Three devices (3%) were explanted because of lead complications, 1 (1%) because of infection, and 11 (10%) because of inadequate control of atrial fibrillation. In

**TABLE 2. Patient Demographics (n=105)**

<table>
<thead>
<tr>
<th>Category</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, y</td>
<td>59±12 (25–79)</td>
</tr>
<tr>
<td>Gender, n (%)</td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>75 (72)</td>
</tr>
<tr>
<td>Female</td>
<td>30 (28)</td>
</tr>
<tr>
<td>LVEF, %</td>
<td>57±8 (38–78)</td>
</tr>
<tr>
<td>LA size, cm</td>
<td>4.5±2.1 (3.3–8.0)</td>
</tr>
<tr>
<td>NYHA class (SR), n (%)</td>
<td></td>
</tr>
<tr>
<td>I</td>
<td>83 (84)</td>
</tr>
<tr>
<td>II</td>
<td>16 (16)</td>
</tr>
<tr>
<td>NYHA class (AF), n (%)</td>
<td></td>
</tr>
<tr>
<td>I</td>
<td>61 (75)</td>
</tr>
<tr>
<td>II</td>
<td>11 (14)</td>
</tr>
<tr>
<td>III</td>
<td>8 (10)</td>
</tr>
<tr>
<td>IV</td>
<td>1 (1)</td>
</tr>
<tr>
<td>Structural heart disease, n</td>
<td></td>
</tr>
<tr>
<td>None</td>
<td>27</td>
</tr>
<tr>
<td>Hypertension</td>
<td>46</td>
</tr>
<tr>
<td>Coronary artery disease</td>
<td>22</td>
</tr>
<tr>
<td>Previous MI</td>
<td>8</td>
</tr>
<tr>
<td>PTCA</td>
<td>12</td>
</tr>
<tr>
<td>CABG</td>
<td>9</td>
</tr>
<tr>
<td>Valvular heart disease</td>
<td>36</td>
</tr>
<tr>
<td>Repair/replacement</td>
<td>2</td>
</tr>
<tr>
<td>Congenital heart disease</td>
<td>2</td>
</tr>
<tr>
<td>Cardiomyopathy</td>
<td>2</td>
</tr>
</tbody>
</table>

LVEF indicates left ventricular ejection fraction; LA, left atrium; SR, sinus rhythm; AF, atrial fibrillation; and MI, myocardial infarction. Data are presented as mean±SD (range) when appropriate. n=105.

**TABLE 3. Antiarrhythmic Drug Therapy**

<table>
<thead>
<tr>
<th>Category</th>
<th>Last Follow-Up, n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>None</td>
<td>9 (9)</td>
</tr>
<tr>
<td>Rate control only</td>
<td>14 (13)</td>
</tr>
<tr>
<td>Class I</td>
<td>23 (22)</td>
</tr>
<tr>
<td>Class III</td>
<td>24 (23)</td>
</tr>
<tr>
<td>Sotalol</td>
<td>35 (33)</td>
</tr>
</tbody>
</table>

n=105.
the 105 patients, 18 of the 270 leads (7%) implanted required repositioning (9 right atrial leads and 9 right ventricle leads). The coronary sinus lead did not dislodge in any patient. The mean follow-up was 11.7 ± 6.8 months.

**Outpatient Defibrillator Therapy Before Transition to Ambulatory Therapy**

Seventy-five patients had 412 episodes of atrial fibrillation for which they sought therapy (Figure 3). Of these 412 episodes, 388 were treated with 897 shocks delivered from the atrial defibrillator. The atrial defibrillator restored sinus rhythm in 368 of the 388 episodes (95%); however, atrial fibrillation recurred within minutes after successful cardioversion for 95 episodes (26%). For 54 of the 95 episodes in which early recurrence of atrial fibrillation occurred during the treatment of an episode, sinus rhythm was eventually restored with additional shocks from the atrial defibrillator with or without the administration of antiarrhythmic drugs. Taking into account the remaining 41 of the 95 episodes where early recurrences were observed and could not be successfully treated, the therapy efficacy was 85%.

**Ambulatory Defibrillator Therapy**

At the time of the most recent follow-up, 48 patients fulfilled all criteria and agreed to receive ambulatory therapy (Figure 3). The mean follow-up after transition to ambulatory therapy was 8.4 ± 3.7 months. For 6 patients, the device was programmed to the automatic mode, and for 42 patients, the device was programmed to the patient-activated mode. Table 4 outlines the programmed number of shocks and their intensity for 43 of 48 patients in whom these data were available. The mean number of shocks programmed was 2.1 ± 1.0, with a median of 2. No patients had >4 shocks programmed. The first shock voltage was programmed to the maximum output of 300 V for 28 of the 43 patients (65%). Second, third, and fourth shocks were always programmed to maximum output in all patients. A warning shock was programmed for 18 patients (42%). In most patients, this low-voltage shock was delivered within 5 minutes before delivery of the therapeutic shock.

Of the 48 patients, 37 patients had 301 episodes of atrial fibrillation for which they desired therapy. Complete data to assess therapy outcome were available for 296 of 301
episodes (98%). The average number of episodes per patient was $8\pm10$ (range, 1 to 43), with a median of 4 episodes per patient. The adjusted monthly episode rate for this patient population was $1.4\pm1.0$ episodes per patient-month (range, 0.1 to 4.6), with a median of 1.2.

A total of 365 shocks were delivered for ambulatory therapy, and all shocks were appropriate. Atrial fibrillation was confirmed by stored electrograms. No shocks were delivered during sinus rhythm. The mean number of shocks required to treat each episode of atrial fibrillation was $1.6\pm1.2$ (range, 1 to 8), with a median of 1 shock per episode. In 276 of the 296 episodes of atrial fibrillation in which the number of shocks delivered was known, 191 episodes (69%) were successfully treated with 1 shock, and only 22 episodes (8%) required $\geq$3 shocks.

The outcome of the 296 episodes is summarized in Figure 3. For 265 of 296 episodes of atrial fibrillation (90%), the patient attempted to treat the episode. The atrial defibrillator successfully converted 199 of 265 episodes (75%), and therapy failed to successfully convert 52 episodes (25%). The remaining 14 episodes did not result in defibrillator therapy delivery because normal device function precluded delivery of therapy as a result of a high ventricular rate, but the patient did not correctly activate the device with the magnet, or the patient deactivated the device after initial activation. Of the 66 episodes of atrial fibrillation that were not successfully treated or for which no shock was delivered, 34 (51%) converted spontaneously after failed device therapy ($n=22$ of 52) or after therapy was not delivered ($n=12$ of 14).

For the remaining 31 of 296 episodes of atrial fibrillation, patients chose to return to the clinic or hospital for therapy for 27 episodes, and atrial fibrillation converted spontaneously for 4 episodes. Atrial fibrillation also converted spontaneously in 4 of the 27 episodes for which the patient chose to return to the clinic/hospital for device therapy.

The 55 sustained episodes of atrial fibrillation were treated under physician observation (bottom of Figure 3). Of these 55 episodes, 49 (89%) were successfully treated with the atrial defibrillator, 5 episodes failed to be terminated and later reverted spontaneously to sinus rhythm, and 1 episode terminated before device activation.

Considering episodes of atrial fibrillation that were converted with the defibrillator in the ambulatory setting, the efficacy was 75% (199 of 265), and the therapy efficacy (including device therapy delivered in a clinic/hospital setting) was 90% (248 of 275). Therapy efficacy was 100% in 70% of patients. Among the 37 patients experiencing only 1 episode of atrial fibrillation, the atrial defibrillator failed to cardiovert the episode in only 3 patients (8%).

### Safety of Shock Therapy
During this study, there were 5523 shocks delivered from the atrial defibrillator; 365 shocks were delivered during ambulatory therapy. An additional 897 shocks were delivered to treat episodes of atrial fibrillation before the patient’s transition to ambulatory therapy. The remaining 4261 shocks were delivered for atrial fibrillation induction and defibrillation testing. All shocks were delivered with appropriate synchronization, and there were no episodes of ventricular proarrhythmia. Considering the number of shocks per patient and the number of patients enrolled, the 95th percentile upper CI of risk of proarrhythmia was 0.056% per shock. Assuming the median monthly episode rate and shocks per episode as reported in this study, the maximum annual risk of proarrhythmia was 0.81%.

### Perception of Ambulatory Therapy
The impact of event scores was available from 143 treated episodes (25 patients). The mean number of episodes per patient was $5.7\pm6.1$ (range, 1 to 32), with a median of 4.

The average symptom severity score was not significantly different between episodes that were successfully treated and those that were unsuccessfully treated ($6.3\pm2.0$ versus $5.2\pm1.8$, $P>0.05$). The overall severity index was $6.1\pm1.9$. Similarly, there was no significant difference between successfully and unsuccessfully treated episodes with respect to discomfort ($5.2\pm2.5$ [median, 5.0] versus $4.2\pm2.2$ [median, 4.0], $P>0.05$). Patients did have significantly higher satisfaction scores associated with successful compared with unsuccessful therapies ($8.7\pm1.3$ [median, 9] versus $3.4\pm3.3$ [median, 2], $P<0.05$). Patients reported relief of symptoms after treatment of 83% of episodes.

### Discussion

#### Main Findings
The main findings of this study are that an implanted atrial defibrillator can safely be used for outpatient electrical cardioversion of symptomatic atrial with high patient satisfaction. With about a 1-year follow-up, overall defibrillator efficacy was 90%, and $\approx 70\%$ of the atrial fibrillation episodes were successfully treated with a single shock. There was no ventricular proarrhythmia. These findings are consid-

<table>
<thead>
<tr>
<th>Table 4. Programmed Parameters for Ambulatory Therapy</th>
<th>Patients, n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Shocks programmed, n</td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>12 (28)</td>
</tr>
<tr>
<td>2</td>
<td>20 (47)</td>
</tr>
<tr>
<td>3</td>
<td>6 (14)</td>
</tr>
<tr>
<td>4</td>
<td>5 (12)</td>
</tr>
<tr>
<td>First shock voltage, V</td>
<td></td>
</tr>
<tr>
<td>220</td>
<td>2 (5)</td>
</tr>
<tr>
<td>240</td>
<td>1 (2)</td>
</tr>
<tr>
<td>260</td>
<td>12 (28)</td>
</tr>
<tr>
<td>300</td>
<td>28 (65)</td>
</tr>
<tr>
<td>Second shock voltage, V</td>
<td></td>
</tr>
<tr>
<td>300</td>
<td>32 (100)</td>
</tr>
<tr>
<td>Third shock voltage, V</td>
<td></td>
</tr>
<tr>
<td>300</td>
<td>11 (100)</td>
</tr>
<tr>
<td>Fourth shock voltage V</td>
<td></td>
</tr>
<tr>
<td>300</td>
<td>5 (100)</td>
</tr>
<tr>
<td>Warning shock</td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>18 (42)</td>
</tr>
<tr>
<td>No</td>
<td>25 (58)</td>
</tr>
</tbody>
</table>

$n=43$.
erably better than after 1 year of pharmacological therapy, in which sinus rhythm is maintained in only 50% to 70% of patients\(^9,10\) and the risk of proarrhythmia is \(\approx 2\%\) to 7%.\(^11,12\)

In addition, successful atrial defibrillation was associated with moderate discomfort and high patient satisfaction scores. These findings suggest that ambulatory use of an atrial defibrillator provides safe, successful, and tolerable conversion of atrial fibrillation.

**Absence of Proarrhythmia**

With correct R-wave synchronization and timing to ensure that shock therapy is not delivered during the ventricular relative refractory period, no ventricular proarrhythmia was observed with delivery of \(\geq 5000\) shocks. Although the mean left ventricular ejection fraction was normal, structural heart disease was present in most patients. The results of this study therefore confirm the findings of other studies\(^5,6,8\) that the risk of inducing a ventricular tachyarrhythmia as a result of atrial defibrillation is negligible and extend these findings to ambulatory therapy.

**Patient Tolerance of Shock Therapy**

In previous studies, patients undergoing internal defibrillation tolerated fewer high-intensity shocks (3 to 6 J) better than multiple low-intensity shocks (1 to 3 J).\(^5,13,14\) In this study, most atrial fibrillation episodes could be treated with a single shock, and most first shocks were programmed to maximum output. This high rate of single-shock success likely enhanced patient tolerance of shock-induced discomfort.\(^7\) There are other factors that may influence patient acceptance of shock therapy. Clinical, social, and psychological factors, such as severity of symptoms associated with atrial fibrillation, previous uncomfortable or painful experiences, surrounding stimuli, and convenience of ambulatory and timely therapy, may also affect patient tolerance.\(^15\) In the present study, a questionnaire evaluating the impact of ambulatory therapy showed high patient satisfaction with only moderate discomfort.

**Early Recurrence of Atrial Fibrillation**

In an earlier study\(^5\) in which the atrial defibrillator was tested at the time of implantation, an important limitation was the 27% rate of early recurrence of atrial fibrillation. The present study demonstrates that early recurrence of atrial fibrillation is also an important clinical problem when device therapy is delivered in the outpatient or ambulatory setting. In the ambulatory setting, even though stored electrograms occasionally documented early recurrences of atrial fibrillation (Figure 2), its exact incidence could not be determined once the patient was treated away from the physician. From the rate of early recurrences before transition, it is likely that early recurrence of atrial fibrillation was mostly responsible for the 25% failure rate of outpatient device therapies.

**Previous Studies**

Studies of transvenous atrial defibrillation have demonstrated that most patients with paroxysmal, persistent, and permanent atrial fibrillation can be reliably cardioverted.\(^2\)–\(^4,13,16–18\) Recently, the efficacy of the atrial defibrillator was demonstrated in patients meeting strict implantation criteria.\(^5\) In this initial study, atrial defibrillation was performed under physician observation, and the efficacy was similar to the results in this study. Therefore, the present study demonstrates that ambulatory therapy with the atrial defibrillator is efficacious and is not adversely affected by the absence of physician intervention.

**Impact of Ambulatory Therapy**

It is important to speculate on the impact of out-of-hospital defibrillation on the cost of care and quality of life. Patients with frequent episodes of atrial fibrillation, similar to the patients included in this study who had frequent contact with the healthcare system, often use the healthcare system at a significant cost.\(^16,17\) In the present study, the efficacy of ambulatory therapy was high, which would likely result in fewer emergency room visits and hospitalizations. Even for episodes in which ambulatory therapy was unsuccessful, the patient did not require hospitalization to restore sinus rhythm. Furthermore, as demonstrated in this study, cardioversion of atrial fibrillation relieved symptoms and thus may also improve the patient’s quality of life.\(^18\) Additional studies are needed to prospectively evaluate the cost-effectiveness of ambulatory atrial defibrillation with an implanted device.

**Study Limitations**

Antiarrhythmic therapy was not controlled in this study; therefore, no evaluation of its effect on atrial fibrillation could be made. However, despite antiarrhythmic therapy, patients continued to experience symptomatic atrial fibrillation. A second limitation is that these results are applicable only to patients with frequently recurring, drug-refractory, symptomatic atrial fibrillation. These results cannot be extended to patients with depressed left ventricular ejection fraction or other conditions that may be associated with a higher risk of ventricular arrhythmias. A third limitation is that fewer than the total patients implanted were transitioned to receive ambulatory therapy. The primary reason for not transitioning to ambulatory therapy was that strict criteria for transition were defined in this preliminary trial to guard against life-threatening ventricular proarrhythmia. Repeated confirmations of successful detection and conversion of atrial fibrillation, without early recurrence, were necessary before ambulatory therapy was begun. However, the total number of delivered therapies was quite high and confirms the safety of ambulatory use of an atrial defibrillator. A final limitation is that patients were instructed to complete an impact-of-event questionnaire immediately after delivery of ambulatory therapy. A drawback of this type of survey is that the data collection is dependent on nonmedical personnel to complete and return the questionnaire. Compliance therefore was not 100%.

**Clinical Implications**

An implantable atrial defibrillator needs to satisfy several requirements to achieve therapeutic success in the ambulatory treatment of atrial fibrillation. The defibrillator must accurately detect atrial fibrillation, properly synchronize shocks, and successfully cardiovert atrial fibrillation in a tolerable
manner, preferably one controlled by the patient. This study confirms that the Metrix implanted atrial defibrillator is effective at detecting and terminating atrial fibrillation without induction of ventricular proarrhythmia. Although patients perceived shock therapy as moderately uncomfortable, patient satisfaction with the therapy was high. Whether an atrial defibrillator is cost-effective and improves quality of life remains to be determined.

References
Initial Clinical Experience With Ambulatory Use of an Implantable Atrial Defibrillator for Conversion of Atrial Fibrillation

Emile G. Daoud, Carl Timmermans, Chris Fellows, Robert Hoyt, Robert Lemery, Kathy Dawson and Gregory M. Ayers
for the Metrix Investigators

_Circulation_. 2000;102:1407-1413
doi: 10.1161/01.CIR.102.12.1407

_Circulation_ is published by the American Heart Association, 7272 Greenville Avenue, Dallas, TX 75231
Copyright © 2000 American Heart Association, Inc. All rights reserved.
Print ISSN: 0009-7322. Online ISSN: 1524-4539

The online version of this article, along with updated information and services, is located on the World Wide Web at:
http://circ.ahajournals.org/content/102/12/1407

Permissions: Requests for permissions to reproduce figures, tables, or portions of articles originally published in _Circulation_ can be obtained via RightsLink, a service of the Copyright Clearance Center, not the Editorial Office. Once the online version of the published article for which permission is being requested is located, click Request Permissions in the middle column of the Web page under Services. Further information about this process is available in the Permissions and Rights Question and Answer document.

Reprints: Information about reprints can be found online at:
http://www.lww.com/reprints

Subscriptions: Information about subscribing to _Circulation_ is online at:
http://circ.ahajournals.org//subscriptions/