Radiofrequency Catheter Ablation of Type 1 Atrial Flutter Using Large-Tip 8- or 10-mm Electrode Catheters and a High-Output Radiofrequency Energy Generator

Results of a Multicenter Safety and Efficacy Study

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Atrial flutter (AFL) is a common arrhythmia that can be cured by radiofrequency (RF) catheter ablation of the tricuspid valve (TV)-inferior vena cava (IVC) isthmus (1–8). With the demonstration of bidirectional conduction block across the TV-IVC isthmus after ablation, long-term efficacy has increased to >90% (9). Nevertheless, when using standard 4- and 5-mm electrode-tipped catheters and an RF generator with a maximum power of 50 W, ablation may be difficult in some cases, requiring multiple energy applications and prolonged procedure and fluoroscopy times (1–9).

Consequently, the efficacy of ablation catheters with longer electrodes (i.e., >5 mm), or saline irrigated electrodes has been investigated (10–14). Large-tip ablation catheters and irrigated tip ablation catheters have a theoretical advantage because they can produce a larger ablation lesion (14). However, in the case of longer ablation electrodes that have a larger surface area, a higher power RF generator (i.e., >50 W) is required to produce adequate ablation temperatures (15). The potential advantages of using large-tip electrode ablation catheters with a high power RF generator include the need for fewer energy applications to produce bidirectional isthmus block, shorter procedure and fluoroscopy times, and greater efficacy.

Therefore, we investigated the safety and efficacy of AFL ablation using 8- and 10-mm electrode ablation catheters and a high output 100-W RF generator in a multi-center study.

METHODS

This study was designed to evaluate the safety and efficacy of the EPT-1000 XP Cardiac Ablation System (Boston Scientific Corp., Natick, Massachusetts), consisting of 8- or 10-mm ablation electrode catheters and a 100-W RF generator for ablation of type 1 AFL, in a multicenter, prospective registry. The primary study end points were short- and long-term (six-month) success, defined as bidirectional isthmus block and a lack of recurrence of type 1 AFL, respectively. An additional end point was the com-
Ablation of AFL With Large-Tip Catheters

Ablation was performed during sinus rhythm or AFL, using either an 8-mm (straight or contoured tip) or 10-mm (straight tip) tipped investigational electrode catheter. The electrode tip size used in each case was determined by the investigator at each site in a nonrandomized manner, with instructions from the sponsor to utilize approximately equal numbers of both 8- and 10-mm electrode tip catheters at each study site. Using either an interrupted or continuous drag technique from the TV annulus to the IVC, ablation was performed beginning at a power of 50 W (maximum of 100 W), for up to 120 s, with a maximum target temperature of 70°C. After each attempt isthmus ablation, the presence or absence of bidirectional isthmus conduction block was assessed during pacing from the coronary sinus ostium and low lateral right atrium at a cycle length ≥600 ms. Ablation was repeated until isthmus block was achieved or the investigator determined that ablation using the investigational device was unsuccessful. Bidirectional isthmus block was confirmed by demonstrating a fully descending wavefront of activation in the contralateral atrial wall during pacing from the coronary sinus ostium and low lateral right atrium, respectively. Additional criteria confirming bidirectional isthmus block included recording of double potentials at the TV-IVC isthmus during pacing from the coronary sinus ostium and low lateral right atrium. Anticoagulation with heparin during the procedure was performed at the discretion of the investigator.

POST-ABLATION EVALUATION. After ablation, assessment of TV-IVC isthmus conduction was performed periodically for up to 30 min to ensure persistent isthmus block. Burst pacing was also performed at cycle lengths down to 2:1 capture or to a minimum cycle length of 180 ms from the low lateral right atrium and coronary sinus ostium to confirm that AFL was not inducible. If type 1 AFL (CW or CCW) was re-induced or resumption of unidirectional or bidirectional TV-IVC isthmus conduction was demonstrated, ablation was repeated in the same or an alternate location in the isthmus until isthmus block was achieved and AFL was no longer inducible, or the investigator determined that the procedure was unsuccessful using the investigational device.

Postprocedural evaluation. All patients were evaluated by repeat ECG and two-dimensional echocardiography within 72 h after ablation. All patients were instructed to use a patient-activated event monitor (LifeWatch, Chicago, Illinois) to telephonically transmit a rhythm strip weekly and for any symptoms suggesting arrhythmia recurrence. After ablation, anticoagulation with warfarin was performed at the discretion of the investigator.

Each patient was evaluated in the clinic at one, three, and six months after ablation. During all follow-up visits, patients were interviewed for anti-arrhythmic and cardiac

Abnormalities and Acronyms

- AFL = atrial flutter
- CCW = counterclockwise
- CW = clockwise
- IVC = inferior vena cava
- QOL = quality of life
- RF = radiofrequency
- TV = tricuspid valve

Enrollment in this study did not require failure of anti-arrhythmic therapy for type 1 AFL. However, a history of anti-arrhythmic therapy was obtained and reported.

Preprocedural evaluation. Written, informed consent was obtained from all patients. A complete history was obtained, including demographic data, pertinent past medical history, and symptom and treatment history, and a physical examination was performed. A 12-lead electrocardiogram (ECG) and two-dimensional echocardiogram were obtained for each patient. A QOL questionnaire was completed by each patient. A QOL questionnaire was completed by each patient. A QOL questionnaire was completed by each patient.

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Study inclusion criteria included: 1) AFL defined as an atrial rate between 240 and 350 beats/min, unless modified by class 1c anti-arrhythmic drugs or amiodarone down to 200 beats/min; 2) one or more episodes of AFL documented within six months before enrollment; 3) two or more patient-reported symptoms of AFL during the previous 12 months; 4) demonstration by endocardial recordings of clockwise (CW) or counterclockwise (CCW) isthmus-dependent type 1 AFL; and 5) age <80 years and >18 years.

Ablation was performed. Ablation was performed. Ablation was performed. Ablation was performed. Ablation was performed. Ablation was performed. Ablation was performed.
medication use. At the one, three, and six–month follow-up visits, a physical examination and 12-lead ECG were performed. At each evaluation, careful attention was given to event monitor recordings, hospital or emergency room visits, and any cardiovascular events that may have occurred since ablation. In addition, each patient was contacted by telephone at 12 and 24 months and asked a series of questions regarding any recurrence of arrhythmia-related symptoms and any change in medical condition that would indicate a possible AFL recurrence or adverse event.

Each patient was asked to complete three health-related QOL survey instruments on a regular basis during the study. These surveys were administered upon study entry (baseline) and at one, three, and six months after ablation. These surveys included the following: 1) the Short-Form 36 (SF-36), a 36-item survey characterizing the patient’s general health and well being; 2) the Symptom Assessment survey, a nine-item instrument relating to symptomatology; and 3) the Global Health Assessment, a single-item visual analog scale used to assess the patient’s overall health.

**Primary efficacy end points.** Short-term success was defined as bidirectional isthmus block with no inducible type 1 AFL, achieved using only the investigational device. Long-term success was defined as continued absence of type 1 AFL for six months after ablation.

**Secondary efficacy end points.** Technical success was defined as bidirectional isthmus block with no inducible type 1 AFL after ablation, using either the investigational device or a standard device. Case and fluoroscopy times consistent with those reported in the medical literature. Demonstration that different tip configurations provide similar technical success rates. Change or improvement from baseline in QOL scores.

**Safety end points.** The primary safety end point was occurrence of a major complication, defined as a serious adverse event occurring within seven days of the index procedure.

Other methods used to assess patient safety included weekly event monitor transmissions, clinical assessments at one, three, and six months, and event monitor transmissions triggered by symptoms.

A Clinical Events Committee provided input in the review and evaluation of reported adverse events. A Data Safety Monitoring Board periodically reviewed safety data to determine the risk and benefit of the study treatment.

**Statistical analysis.** The study was a single-arm trial to evaluate the safety and efficacy of the EPT-1000 XP Cardiac Ablation System for treatment of type 1 AFL. The study sample size provided 80% power for evaluating short-term success, complication rate, and six-month success. Additional subgroup analyses are presented along with their corresponding p values.

All statistical analyses were done using SAS Version 8 Software (SAS Institute Inc., Cary, North Carolina). Patient demographics, clinical history, risk factors, pre- and post-procedural lesion characteristics, procedural character-

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### Table 1. Clinical Characteristics of Patients (n = 169)

<table>
<thead>
<tr>
<th>Variable</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (yrs)</td>
<td>61 ± 12</td>
</tr>
<tr>
<td>Gender (M/F)</td>
<td>138/31</td>
</tr>
<tr>
<td>Structural heart disease</td>
<td>82 (49%)</td>
</tr>
<tr>
<td>LAE</td>
<td>95 (56%)</td>
</tr>
<tr>
<td>RAE</td>
<td>47 (28%)</td>
</tr>
<tr>
<td>LVEF &gt;50%†</td>
<td>112 (66%)</td>
</tr>
<tr>
<td>LVEF &lt;50%</td>
<td>41 (24%)</td>
</tr>
<tr>
<td>Prior AA drugs (class I or III)</td>
<td>39 (23%)</td>
</tr>
<tr>
<td>CCW type 1 AFL†</td>
<td>129 (76%)</td>
</tr>
<tr>
<td>CW type 1 AFL</td>
<td>31 (18%)</td>
</tr>
<tr>
<td>CCW and CW type 1 AFL</td>
<td>4 (3%)</td>
</tr>
</tbody>
</table>

*LVEF not evaluated in 16 patients (9%).†Morphology of AFL was not documented before ablation in 5 patients (3%). Data are presented as the mean value ± SD or number (%) of patients.

AA = anti-arrhythmic; AFL = atrial flutter; CCW = counterclockwise; CW = clockwise; LAE = left atrial enlargement; LVEF = left ventricular ejection fraction; RAE = right atrial enlargement.

Multivariable model analyses were performed using logistic regression to examine covariates as possible predictors of short-term success, complication rate, and six-month success. The covariates used were gender and a history of heart disease, thromboembolic events, and stroke. A forward model building procedure was used to determine which covariates were possible predictors of the primary end points listed previously. In addition, these covariates were individually tested for univariable association with the primary end points, using the Fisher exact test with two-tailed significance.

Differences between 8- and 10-mm tip ablation electrodes were evaluated for short-term success, complication rate, six-month success, number of ablations required, and procedure and fluoroscopy times, using the Fisher exact test and the Wilcoxon rank-sum test with two-tailed significance.

Furthermore, an analysis was performed to identify any association between use of high power and occurrence of major device-related complications, using both the Fisher exact test and logistic regression.

**RESULTS**

**Patient population.** A total of 1,076 patients with a diagnosis of AFL were screened for the study, 169 of whom met all inclusion criteria and were enrolled (Table 1). There were 138 (82%) male and 31 (18%) female patients enrolled in the study, with an average age of 61 ± 12 years. Nearly one-half (82 [49%] of 169) reported a history of structural heart disease. Ninety-five (56%) patients had left atrial enlargement, 47 (28%) had right atrial enlargement, 40 (23%) had left ventricular enlargement, and 23 (14%) had right ventricular enlargement. Preprocedural left ventricular ejection fraction was >50% in 112 (66%) patients, <50% in 41 (24%) patients, and not evaluated in 16 (9%) patients. Thirty-nine (23%) patients had been treated with a class I-A, I-C, or III anti-arrhythmic
drug in the past, whereas 130 (77%) patients had received no previous treatment. At the time of ablation, 42 (24%) patients were receiving a class I-A, I-C, or III anti-arrhythmic drug, whereas 127 (75%) patients were not being treated. Thirty-two (19%) patients reported a history of atrial fibrillation, for which the average interval between the last treatment and the investigational procedure was 105 days. Patients were excluded if they had been treated for non-AFL arrhythmias within three months before the procedure. On the ECG, immediately before ablation, 95 (56%) patients were noted to be in AFL, 72 (43%) in sinus rhythm, 1 (1%) in atrial tachycardia, and 1 (1%) in atrial fibrillation (induced during electrophysiologic study). Counterclockwise AFL was present or induced in 129 (76%) patients before ablation, 31 (18%) patients had CW AFL, and 4 (3%) had both. In 5 (3%) patients, the morphology of AFL was not documented on case-report forms.

Anticoagulation was prescribed according to standards at each investigative center, rather than by protocol requirement. Thus, warfarin was administered before ablation in only 43% of patients and at discharge in 55% of patients. Warfarin therapy was then continued in 56%, 45%, and 30% of patients at 1-, 3-, and 6-month follow-up, respectively. Intravenous heparin was used in only 22% of patients during ablation.

**Short-term results of ablation.** In this study, 158 (93%) of 169 patients achieved short-term success (Fig. 1), whereas the procedure failed in 11 (7%) patients. The mean procedure time was 2.03 ± 1.12 h, with a mean ablation time of 39.0 ± 41.4 min and a mean fluoroscopy time of 28.4 ± 19.5 min.

A mean of 12 ± 11 RF energy applications were delivered per patient. The median number of RF applications needed to terminate AFL was three. The median number of RF applications required to achieve bidirectional isthmus block...
was 7, and 75% of patients had bidirectional isthmus block achieved with 13 or fewer RF applications. The median number of RF applications delivered per patient was nine, with the 75th percentile at 16 lesions, and 25% of patients had three or more “insurance burns” (i.e., lesions delivered after bidirectional block was achieved). The mean duration of each RF application was 73 ± 8 s. The mean power setting used was 78 ± 17 W, whereas the mean power actually delivered to achieve the target temperature was 55 ± 20 W. The mean temperature setting used was 64 ± 8°C, whereas the mean temperature actually achieved was 54 ± 6°C.

The procedure was performed in the majority of patients (150 [89%] of 169), with only one investigational catheter. Two investigational catheters were used in 14 (8%) patients, and three catheters were used in 5 (3%) patients. The reasons for the use of multiple catheters during a procedure included investigator preference, differences in patient anatomy, stability in positioning, and the need for different catheter sizes.

For patients in whom only one catheter was used to achieve short-term success (n = 150), the 10-mm straight-tip catheter was used most often (49%), followed by the 8-mm straight-tip catheter (35%), and lastly, the 8-mm contoured tip catheter (17%). There was no significant difference in short-term efficacy between these three ablation electrodes: 69 (95%) of 73 patients with the 10-mm straight tip, 51 (98%) of 52 patients with the 8-mm straight tip, and 24 (96%) of 25 patients with the 8-mm contoured tip (p = NS). However, the mean number of RF applications required to achieve short-term success was 10 ± 8 with the 10-mm tip versus 14 ± 8 with the 8-mm tip (p = 0.002). The mean time required for ablation was 0.5 ± 0.4 h with the 10-mm tip versus 0.8 ± 0.6 h with the 8-mm tip (p = 0.0002). Data using the 8-mm contoured tip catheter were not included in this statistical analysis, because these 25 patients were treated at a single institution, which would not allow for a fair comparison of results across the entire study population. At this institution, successful ablation with the contoured tip required a mean of 6 ± 5 RF applications and a mean ablation time of 0.3 ± 0.3 h. Analysis of the effect of maximum applied power on short-term success, as well as the number or duration of RF applications, revealed no significant difference between deciles from <50, 50 to 60, 60 to 70, or >70 W delivered.

At the conclusion of the ablation procedure, 96% of patients were in normal sinus rhythm. In patients who had the A-H interval measured both before and after ablation, there was no significant difference (90.7 ± 28.2 ms vs. 90.9 ± 27.5 ms). The H-V interval was also not significantly different before and after ablation (50.5 ± 13.7 ms vs. 50.9 ± 17.0 ms).

**Long-term results of ablation.** Of the 158 patients with short-term success (Fig. 1), 42 patients were not evaluated for long-term success at six months because of either use of anti-arrhythmic drugs for treatment of recurrent arrhythmias other than AFL (n = 20), death (n = 4), bradycardia requiring pacemaker implantation (n = 11), persistent atrial fibrillation (n = 1), voluntary withdrawal from the study (n = 4), or a lack of follow-up (2). Of the 116 patients who were evaluated at six months, 112 (97%) had no recurrence of AFL. There was no ventricular tachycardia documented in any patient. These results were derived from both symptom-triggered and scheduled event monitor transmissions, for which there was high compliance in 96% of patients (defined as transmission achieved during at least two-thirds of all scheduled follow-up events).

In addition, among the 112 patients evaluated at six months who had no AFL recurrence, telephone contact at 12 and 24 months revealed that 95% (93 of 98 patients) and 93% (78 of 84 patients), respectively, remained free of arrhythmia-related symptoms.

**Effects of AFL ablation on QOL.** The ablation of AFL in this study population resulted in a statistically significant improvement in QOL scores at three- and six-month follow-up (Table 2), including seven of 10 items contained in the SF-36 survey (p < 0.05), the Global Health Assessment survey (p < 0.01), and the Symptom Assessment survey (p < 0.01). Among the 158 patients with short-term

<table>
<thead>
<tr>
<th>Item</th>
<th>Baseline</th>
<th>3 Months</th>
<th>6 Months</th>
<th>Follow-Up</th>
<th>p Value†</th>
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</thead>
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<tr>
<td>Physical component summary</td>
<td>42.4</td>
<td>46.9</td>
<td>46.1</td>
<td>45.9</td>
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<td>Physical functioning</td>
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<td>76.4</td>
<td>76.2</td>
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<td>Role—physical</td>
<td>42.9</td>
<td>73.5</td>
<td>67.3</td>
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<td>Bodily pain</td>
<td>72.7</td>
<td>76.8</td>
<td>72.4</td>
<td>73.3</td>
<td>0.74</td>
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<td>51.7</td>
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<td>Vitality</td>
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<td>Social functioning</td>
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<td>78.5</td>
<td>79.2</td>
<td>0.029</td>
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<tr>
<td>Feeling thermometer</td>
<td>70.7</td>
<td>79.6</td>
<td>78.2</td>
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<td>Severity</td>
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<td>6.0</td>
<td>4.8</td>
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<tr>
<td>Frequency</td>
<td>27.7</td>
<td>7.5</td>
<td>6.4</td>
<td>7.6</td>
<td>&lt;0.0001</td>
</tr>
</tbody>
</table>

†Average of follow-up values determined at three- and six-month visits. The p values represent the difference between baseline and follow-up values.

*Table 2. Summary of Health-Related Quality-of-Life Instrument Scores at Baseline and Follow-Up for All Patients Evaluated at Six Months*
success, there was a significant reduction ($p = 0.03$) in anti-arrhythmic drug use at six months after ablation, from 39 (25%) to 19 (15%) patients. Among the 112 patients with no recurrence of AFL at six months, there was also a reduction in anti-arrhythmic drug use, from 23 to 0 patients at six months after ablation. Among the 158 patients with short-term success in ablation of AFL, at six months after ablation there was a significant reduction ($p < 0.05$) in the number of patients taking rate-control drugs (i.e., beta-blockers, calcium channel blockers, and digitalis glycosides), from 85 (54%) to 43 (34%) patients. Among the 112 patients with no recurrence of AFL, at six months after ablation there was a significant reduction ($p < 0.05$) in the number of patient taking rate-control drugs, from 58 (52%) to 34 (31%) patients.

Adverse events associated with ablation of AFL. There were eight major adverse events in 6 (3.6%) of the 169 patients treated in this study. These major adverse events included pulmonary embolism ($n = 1$), fractured femur ($n = 1$), bilateral lower extremity ischemia due to systemic thromboembolism ($n = 1$), deep venous thrombosis ($n = 1$), right groin hematoma ($n = 1$), cerebral embolus with resolution of neurologic findings ($n = 1$), and cerebral infarct (thrombotic) five days after the procedure with persistent mild aphasia ($n = 1$). Of these major adverse events, the femur fracture (due to an accidental fall) was not caused by the study procedure, and the cerebral embolus and cerebral infarct were associated with a left atrial ablation procedure and intracranial stenosis of right and left middle cerebral arteries, respectively. There were no deaths attributable to the study.

Statistical analysis demonstrated no correlation between these major adverse events and use of high power during ablation (i.e., $>60$ W), ablation electrode size, presence of underlying structural heart disease, stroke, age, or a history of atrial fibrillation. However, there was a significant correlation between the occurrence of a major adverse event and a history of thromboembolic events ($p = 0.0488$).

**DISCUSSION**

The results of this study indicate that ablation of type 1 AFL using 8- or 10-mm electrode-tipped ablation catheters, with a higher power RF energy generator capable of delivering up to 100 W, is safe and highly effective. The data also demonstrate that the 10-mm ablation electrode catheter may allow ablation of AFL to be performed more rapidly and with fewer RF applications compared with the 8-mm ablation electrode catheter.

**Short- and long-term efficacy of large-tip ablation catheters for the cure of AFL.** The results of this study confirm that a high degree of short- and long-term success can be achieved using 8- or 10-mm electrode-tipped ablation catheters with a high-power 100-W RF generator to ablate type 1 AFL. The short- (93%) and long-term (97%) efficacy, ablation and procedure times, number of RF applications, and total duration of RF application observed in this study were comparable to, or better than, those achieved in most recently published studies reporting success rates ranging from 85% to 90% using standard 4- to 5-mm ablation electrode catheters (1–8), as well as 8-mm or irrigated ablation electrode catheters (9–13), with standard 50-W RF generators. Furthermore, this study demonstrated that ablation of AFL required fewer RF applications and a shorter duration of ablation with the 10-mm electrode ablation catheter compared with the 8-mm electrode ablation catheter. Thus, in addition to the comparable or slightly greater efficacy of the large-tip ablation catheters and high-power RF generator used in this study, there are further potential advantages of fewer RF applications and shorter total ablation time required with the 10- versus 8-mm electrode ablation catheter.

**Impact of AFL ablation on QOL measures.** Curative ablation of AFL produced significant improvements in QOL measures, including overall sense of well-being and general health, and a reduction of arrhythmia-related symptoms. Similar findings have been observed in previous studies (16–18). In addition, ablation of AFL was shown to significantly reduce the use of anti-arrhythmic and rate-control drugs compared with baseline, despite the fact that some rate-control drugs may also be used to control hypertension.

**Adverse events related to use of large-tip ablation electrodes and high-power RF generator.** The major adverse event rate (3.6%) in this study was low compared with the rates observed in previous studies for ablation of AFL and other forms of supraventricular tachycardia (1–14,19,20). This low adverse event rate was observed despite the approximately equal use of 8- and 10-mm electrode-tipped ablation catheters and delivery of power in excess of 70 W in many cases. In fact, statistical analysis revealed no correlation between the level of power delivered during ablation and the occurrence of adverse events. Thus, the data clearly indicate that ablation of AFL with large ablation electrodes and a high-power RF generator is at least as safe as ablation with the standard RF catheters and generators currently in use today (1–14,19,20).

Although weak, a statistically significant correlation was observed between a history of thromboembolism and the occurrence of major adverse events, a majority of which were thromboembolic in nature. This observation raises concerns that patients should probably be anticoagulated with warfarin before and for several months after AFL ablation, in order to minimize the risk for thromboembolic complications. Again, however, there was no correlation between the occurrence and type of adverse events and the use of large-tip catheters or high power during ablation.

**Study limitations.** This multicenter, prospective registry study was not designed as a randomized comparative study, which would have allowed a comparison of safety and efficacy between the EPT-1000 XP Cardiac Ablation System using large-tip ablation catheters plus a 100-W RF generator and the standard 4- to 5-mm ablation electrode.
catheters plus 50-W RF generators currently in use today. However, despite the very high efficacy and low adverse event rates observed in this study, compared with the similar or only slightly inferior results in recently published studies using standard systems, there probably would not have been a statistically significant difference in the results.

**Conclusions.** Ablation of AFL using an 8- or 10-mm ablation electrode catheter and high-power 100-W RF generator was highly effective, with short- and long-term success rates of 93% and 97%, respectively. The maximum power required to maintain a target temperature during ablation of AFL with an 8- or 10-mm ablation electrode catheters was frequently high in this study, with a maximum power over 70 W required in 85% of patients. Additionally, the 10-mm ablation electrode catheter required a greater maximum power compared with the 8-mm ablation electrode catheter. Ablation of AFL with an 8- or 10-mm ablation electrode catheter and high-power 100-W RF generator was safe, with a complication rate of only 3.6%. The use of large 8- or 10-mm ablation electrode catheters reduced the ablation and procedure times, number of RF applications required, and total duration of energy application, compared with most published studies using standard 4- to 5-mm ablation electrode catheters. The number of RF energy applications and the total duration of RF application required to cure AFL was significantly lower with the 10-versus 8-mm ablation electrode catheter. Quality-of-life measures were significantly improved after catheter ablation of AFL.

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**APPENDIX**

For a complete list of the investigators and affiliations, please see the April 21, 2004, issue of JACC at www.cardiosource.com/jacc.html.