Prospective Randomized Comparison of Irrigated-Tip Versus Conventional-Tip Catheters for Ablation of Common Flutter

Pierre Jaïs, MD; Dipen C. Shah, MD; Michel Haïssaguerre, MD; Mélèze Hocini, MD; Stéphane Garrigue, MD; Philippe Le Metayer, MD; Jacques Clémenty, MD

Background—Radiofrequency (RF) ablation of common flutter requires the creation of a complete ablation line to produce bidirectional conduction block in the cavotricuspid isthmus. An irrigated-tip ablation catheter has been shown to be effective in patients in whom conventional ablation has failed. This randomized study compares the efficacy and safety of this catheter with those of a conventional catheter for de novo flutter ablation.

Methods and Results—Cavotricuspid ablation was performed with a conventional (n=26) or an irrigated-tip catheter (n=24). RF was applied for 60 minutes with a temperature-controlled mode: 65°C to 70°C up to 70 W with a conventional catheter or 50°C up to 50 W (with a 17-mL/min saline flow rate) with the irrigated-tip catheter. The end point was the achievement of bidirectional isthmus block, and a crossover was performed after 21 unsuccessful applications. Procedural ablation parameters as well as number of applications, x-ray exposure, procedure duration, impedance rise, and clot formation were compared for each group. A coronary angiogram was performed before and after each ablation for the first 30 patients. Complete bidirectional isthmus block was achieved for all patients. Four patients crossed over from conventional to irrigated-tip catheters. The number of applications, procedure duration, and x-ray exposure were significantly higher with the conventional than with the irrigated-tip catheter: 13 ± 10 versus 5 ± 3 pulses, 53 ± 41 versus 27 ± 16 minutes, and 18 ± 14 versus 9 ± 6 minutes, respectively. No significant side effects occurred, and the coronary angiograms of the first 30 patients after ablation were unchanged.

Conclusions—Irrigated-tip catheters were found to be more effective than and as safe as conventional catheters for flutter ablation, facilitating the rapid achievement of bidirectional isthmus block. (Circulation. 2000;101:772-776.)

Key Words: catheter ablation ■ atrial flutter ■ catheters

Common flutter designates a reentrant atrial arrhythmia with a stereotypical surface ECG showing continuous undulation with a sawtooth morphology in the inferior leads. It has a prevalence ranging from 1 in 81 to 1 in 238 hospitalized patients.1 This arrhythmia is usually disabling and resistant to antiarrhythmic drugs, and it carries a potential risk of thromboembolism and tachycardiomyopathy.2,3 Intra- cardiac mapping techniques have demonstrated characteristic propagation in the right atrium resulting in a counterclockwise rotation around the tricuspid annulus.4–6 This reentrant circuit has been shown to be critically dependent on conduction through the isthmus of the atrial myocardium limited by the tricuspid annulus and the inferior vena caval orifice.7 Radiofrequency (RF) ablation of this isthmus, the only curative treatment for common flutter, is now widely performed and is the most common indication for ablation in some centers.5–10 Complete and bidirectional conduction block in the isthmus is the best end point to ensure long-term success.5,11,12 However, the creation of a continuous and transmural lesion along the 1 to 6 cm of the isthmus13 is sometimes difficult or impossible to achieve with current RF technology designed for punctate lesions.9,14 Cooling the ablation electrode by irrigation has been shown to prevent both overheating of the electrode-tissue interface and impedance rise during RF delivery, allowing greater power delivery and larger and deeper lesions.15 Irrigated-tip catheters have been used successfully in patients in whom conventional catheters have failed to create an isthmus block.14 To expedite the curative RF ablation of common flutter, we compared the safety and efficacy of irrigated-tip catheters with those of conventional RF catheters in a prospective and randomized study.

Methods

Fifty-six consecutive patients were screened for the study. Three patients refused to enter the study, and 3 were excluded because of aortic or femoral atherosclerosis precluding femoral artery catheterization and coronary angiography (see below). The study population therefore consisted of 50 patients referred for a de novo RF flutter ablation, 8 women and 42 men, 32 to 85 years old (mean ± SD, 63 ± 11 years). They had been affected by flutter for a mean of
2.5±3.4 years despite the unsuccessful use of 2.4±1.3 antiarrhythmic drugs, including amiodarone in 41. Twenty had structural heart disease, including systemic hypertension in 4, hypertrophic cardiomyopathy in 2, dilated cardiomyopathy in 4, ischemic heart disease in 9, and valvular heart disease in 1. As previously reported, many patients (21 of 50) had a previous history of atrial fibrillation.16

The patients were randomly assigned to ablation with a conventional 4-mm-tip thermocouple catheter (Cordis Webster D curve) or an irrigated 3.5- or 5-mm-tip thermocouple catheter (Cordis Webster Thermocool D curve). The protocol was approved by the hospital ethics committee. Informed consent was obtained from all patients.

Electrophysiological Study and Ablation

Patients were studied in the postabsorptive state under light sedation (midazolam 2 to 5 mg) and/or analgesia (nalbuphine 10 to 20 mg), if required. Two catheters were inserted from the right femoral vein for pacing (Xtrem Medicorp, Viking Bard) and ablation, respectively. Ablation of the cavotricuspid isthmus was performed during flutter in 29 patients and during low lateral right atrial pacing in 21. For patients in flutter, right atrial mapping was performed to demonstrate counterclockwise activation around the tricuspid annulus and through the isthmus with local electrograms centered on the flutter plateau. Electrograms were recorded with a PPG Midas polygraph using high-gain amplification (0.1 mV/cm) and a 30- to 500-Hz bandpass. The linear lesion was made sequentially with coalescent point-by-point ablation lesions (without moving the catheter during RF delivery) from the tricuspid annulus to the inferior vena cava. An SRO long sheath (Daig) was used in case of difficulty in reaching the ventricular side of the cavotricuspid isthmus. To minimize the risk of AV block, coronary artery damage, or perforation, ablation was not performed in the septal isthmus or inside the ostium of the coronary sinus.17

RF energy (550-Hz unmodulated sine-wave output up to 70 W) was delivered through a Cordis Stockert generator with a temperature setting of 65°C to 70°C for 60 seconds at each point with a conventional ablation catheter. The irrigated-tip catheter was used according to a protocol found to be safe in patients in whom isthmus block could not be achieved with conventional RF energy.16 This consisted of temperature-controlled RF delivery with a power limit of 50 W and a target temperature of 50°C applied for 60 seconds at each point. Normal saline (0.9%) was infused through the irrigated-tip catheter with a Gemini Imed pump (battery-powered to avoid 50-Hz line noise) at a rate of 17 mL/min during RF delivery. Between applications, a flow rate of 3 mL/min was used to maintain patency.

The power and temperature achieved, as well as impedance, were noted at 20 seconds during the RF application for all patients. After every 3 applications or after an impedance rise (defined as an elevation of ≥25 Ω), the ablation catheter was removed to note the presence of clot or char on the ablation electrode. No procedural anticoagulation was used.

The end point was fluctulation termination and bidirectional isthmus block demonstrated by activation mapping during pacing from the low lateral right atrium and proximal coronary sinus adjacent to the ablation line.5,11,12 In addition to a complete line of block defined by on-site recording of widely separated local parallel double potentials all along the line.14,18 The double potential included a first component resulting from local activation on the upstream flank of the line, and the second was the latest component of right atrial activation propagating around the tricuspid annulus to the opposite flank of the line. Conduction time from the pacing artifact to the atrial electrogram at the His bundle, at the coronary sinus ostium, and to the second component were measured at the end of the procedure (Figure) and similarly during coronary sinus pacing. If >21 RF applications were unsuccessful,14 the patient crossed over from one group to the other.

A coronary angiogram was systematically performed before and after the isthmus ablation to rule out any asymptomatic coronary damage related to the ablation procedure. At least 2 orthogonal views, usually the 30° right anterior oblique and 60° left anterior oblique views, were performed. After unchanged coronary angio-

grams in 30 patients (including 2 treated by irrigated-tip catheter), coronary angiography was no longer performed, but the surface ECG, physical examination, and stress test were used to assess coronary status.

Postablation Care

Subcutaneous low-molecular-weight heparin (2500 IU) was usually administered once or twice a day if left ventricular function was impaired. Twenty-four-hour Holter recording was performed on day 1 to 3 after ablation, combined with in-hospital telemetry. Twelve-lead ECGs and physical examinations were performed every day to ensure that no side effects, including silent myocardial ischemia, occurred. Transthoracic echocardiography and an exercise stress test were performed 3 to 5 days after the procedure. Patients were discharged on day 5 without antiarrhythmic drugs. Follow-up examination was performed by the referring physician, and information regarding any cardiovascular events was obtained by telephone.

Comparative Analysis and Statistical Methods

The following variables were assessed. The pain related to RF delivery was quantified by the patient between 0 (no pain) and 3 (very painful). The number of applications (lasting ≥20 seconds) required for successful achievement of the end point, procedure duration, x-ray exposure, impedance rise, and presence of clot on the ablation electrode were compared for the 2 groups. Procedure duration was timed from the placement of the introducer sheaths to the removal of all catheters from the heart. Fluoroscopy duration was timed from an automatic fluoroscopy counter during the procedure. For all RF applications, the estimated total energy required was calculated by multiplying the delivered power at 20 minutes by the duration of RF delivery. The number of applications, procedure duration, and x-ray exposure were analyzed on an intention-to-treat basis.

Continuous variables were expressed as mean value±SD and compared by a Mann-Whitney test. The χ² test was used for qualitative variables. Statistical significance was selected at P<0.05.

Results

After randomization, 24 patients were assigned to the irrigated-tip catheter, and 26 were treated with the conventional catheter. There were no differences in sex ratio, age, weight, or structural heart disease between the 2 groups (Table 1).
Efficacy of Flutter Ablation
The end point was achieved for all patients with irrigated-tip catheters and for 22 (85%) with a conventional catheter (\(P=NS\)). After 21 unsuccessful conventional RF applications, 4 patients crossed over and were treated successfully with 1 to 11 additional irrigated-tip catheter applications. Procedural parameters are reported in Table 2 and showed significant differences: 13 ± 6 ± 10 conventional RF applications were required to achieve the complete isthmus block, compared with 5 ± 3 applications in the irrigated-tip group (\(P=0.0003\)). The mean procedure duration and x-ray exposure time in the conventional group (53 ± 6 ± 41 and 18 ± 6 ± 14 minutes, respectively, versus 27 ± 6 ± 16 minutes and 9 ± 6 ± 6 minutes) were approximately twice those in the irrigated-tip group. During ablation, the pain score, 2 ± 1, was similar in the 2 groups. Analgesia was required for 7 patients in the conventional group and 5 in the irrigated-tip group. An SR0 Daig sheath was used for 3 patients in each group. The electrophysiological consequences of the cavotricuspid ablation are shown in Table 3.

In the group of 24 patients treated with the irrigated-tip catheter, the mean power achieved was significantly higher (43 ± 6 ± 3 W) than with the conventional catheter (34 ± 6 ± 14 W). There were very limited variations of the delivered power with the irrigated-tip catheter from one application to another and from one patient to another as opposed to with the conventional catheter, as reflected by differences in SD. However, despite a higher mean delivered power, the estimated total delivered energy was significantly lower with the irrigated-tip catheters (Table 2).

Follow-Up
With a mean follow-up of 5 ± 2 months, all patients but 1 were free of recurrence of flutter. A new ablation procedure was successfully performed in 1 patient treated 2 days earlier with a conventional catheter.

Safety of Flutter Ablation
During ablation, charring on the conventional ablation electrode tip was observed in 20 patients, whereas this was never seen with the irrigated-tip catheter (\(P<0.01\)), including 4 crossover patients in whom 18 instances of catheter-tip char were noted with the conventional catheter. Six instances of impedance rise were observed during RF delivery through the conventional catheter and 1 with the irrigated-tip catheter.

No significant side effects related to RF ablation occurred. However, 1 false femoral aneurysm, which required surgical treatment, developed at the arterial puncture site for a coronary angiogram in a patient in the conventional catheter group. There was no change in the coronary angiogram performed after ablation whichever catheter was used, even in the 5 patients with coronary artery disease (including the right coronary artery in 4). There was no evidence of coronary damage on clinical examination, surface ECG, or stress test for all patients. The transthoracic echocardiography performed after each ablation did not show any significant pericardial effusion.

### Table 1. Study Population Characteristics

<table>
<thead>
<tr>
<th></th>
<th>Conventional Catheter (n=26)</th>
<th>Irrigated-Tip Catheter (n=24)</th>
<th>P</th>
<th>Global Population</th>
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</thead>
<tbody>
<tr>
<td>Sex, No. of women</td>
<td></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td></td>
<td>3</td>
<td>5</td>
<td>NS</td>
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<tr>
<td>Age, y</td>
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<tr>
<td>Associated atrial fibrillation, n</td>
<td>11</td>
<td>10</td>
<td>NS</td>
<td>21</td>
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<tr>
<td>Antiarrhythmic drugs, n</td>
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<td>Structural heart disease, n</td>
<td>10</td>
<td>10</td>
<td>NS</td>
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### Table 2. Procedural Parameters

<table>
<thead>
<tr>
<th></th>
<th>Conventional Catheter (n=26)</th>
<th>Irrigated-Tip Catheter (n=24)</th>
<th>P</th>
</tr>
</thead>
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<tr>
<td>Ablation during flutter, n</td>
<td>11</td>
<td>18</td>
<td>NS</td>
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<tr>
<td>No. of applications for flutter interruption</td>
<td>6±2</td>
<td>3±1</td>
<td>0.001</td>
</tr>
<tr>
<td>No. of applications for isthmus block</td>
<td>13±10 (11)</td>
<td>5±3 (4)</td>
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<td>Crossover, n</td>
<td>4</td>
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<td>NS</td>
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<td>Power delivered at 20 seconds, W</td>
<td>34±14</td>
<td>43±3</td>
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<td>Initial impedance, Ω</td>
<td>113±11</td>
<td>104±12</td>
<td>0.01</td>
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<td>Impedance at 20 seconds, Ω</td>
<td>99±10</td>
<td>90±8</td>
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<tr>
<td>Temperature at 20 seconds, °C</td>
<td>62±3</td>
<td>42±3</td>
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<tr>
<td>Procedure duration, min</td>
<td>53±41 (40)</td>
<td>27±16 (25)</td>
<td>0.0008</td>
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<tr>
<td>X-ray exposure, min</td>
<td>18±14 (13)</td>
<td>9±6 (7)</td>
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<tr>
<td>Cumulative estimated energy, J</td>
<td>22 147±13 293 (20 000)</td>
<td>13 780±7 440 (11 880)</td>
<td>0.01</td>
</tr>
</tbody>
</table>

Values are mean±SD (median).
TABLE 3. Electrophysiological Measurements After Complete and Bidirectional Isthmus Block

<table>
<thead>
<tr>
<th></th>
<th>S-H</th>
<th>S-CS</th>
<th>S-DP2</th>
<th>DP1-DP2</th>
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<td><strong>Mean±SD, ms</strong></td>
<td>108±26</td>
<td>140±27</td>
<td>155±25</td>
<td>117±29</td>
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<tr>
<td><strong>Median, ms</strong></td>
<td>110</td>
<td>140</td>
<td>150</td>
<td>110</td>
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</table>

S-H indicates interval between the pacing artifact (low lateral right atrial pacing close to the ablation line) and the atrial electrogram at the His bundle level; S-CS, interval between pacing artifact and atrial electrogram at the coronary sinus ostium; DP2, second (and latest) potential recorded by the ablation potential on the ablation line; and DP1-DP2, interval between the 2 atrial potentials recorded on the ablation line.

Discussion

This randomized study confirms that RF ablation for typical atrial flutter is effective and safe. However, it demonstrates that the primary use of an irrigated-tip catheter increases the efficacy and considerably simplifies and shortens the RF ablation procedure without compromising safety.

Initially, RF catheter ablation was used to treat focal targets like Wolff-Parkinson-White syndrome and AV nodal reentrant tachycardia or focal atrial tachycardias. The initial 2-mm-tip catheters provided very limited success with RF energy.19 Increasing the ablation electrode size to 4 mm and using steerable catheters was found to produce excellent results in a large majority of patients,20 representing a major advance in the treatment of those arrhythmias.21,22 For the past few years, there has been a shift from focal to linear catheter–based ablation to cure arrhythmias related to reentrant circuits with large critical isthmuses. The most common example is the type 1 flutter, but this is also true for left atrial flutter or multiple reentrant wavelet atrial fibrillation. There is no available catheter for creating long linear lesions with 1 application. Therefore, putative linear lesions are made of adjacent and hopefully coalescent sequential applications.

Different flutter ablation protocols have been reported in the literature, using progressive pullback of the catheter along the isthmus or sequential point-by-point applications of various durations.23–25 In studies that used bidirectional isthmus block as end point, the procedure duration and x-ray exposure reported were usually long. With mainly conventional 4-mm-tip catheters, they ranged from 76 to 197 minutes and 20 to 41 minutes, respectively. In 12 patients treated with an 8-mm-tip catheter, Iesaka et al26 reported a procedure duration of 59±8 minutes and an x-ray exposure time of 26±11 minutes, indicating a slightly better efficiency of these large electrodes. This exposure to x-ray is believed to carry an excess risk of fatal malignancy that is difficult to accept for the treatment of benign arrhythmias.27 In the conventional arm of our study, the procedure duration of 53 minutes is in the lower part of the range, as is the x-ray exposure time of 23 minutes. The significant reduction of procedure and x-ray exposure times observed in patients treated by the irrigated-tip catheters is remarkable. To the best of our knowledge, this is the first time flutter ablation has been performed with <10 minutes of x-ray exposure.

Saline irrigation of the ablation electrode maintains a low electrode-tissue interface temperature, which prevents impedance rise and allows greater RF power delivery, resulting in larger and deeper lesions, thus increasing the likelihood of achieving a continuous and transmural linear lesion. With a conventional catheter, the temperature-controlled mode reduces the occurrence of impedance rise compared with no temperature monitoring, but if the local convective cooling of the electrode is low, the elevation of the electrode temperature dramatically reduces the delivered power and therefore the size of the lesions. The irrigation of the ablation electrode dissociates the delivered power from the local convective cooling. Therefore, a nearly constant and stable amount of power can be delivered effectively for each application (in any location). Moreover, the very limited electrode temperature attained (42°C) prevents any clot or char formation. This point is useful for right-sided ablation by protecting the pulmonary circulation from embolism and is crucial for left-sided ablations.

The major concern with this kind of catheter was considered to be the risk of tamponade and coronary damage related to deeper lesions or “pops” as shown during ablation for the Wolff-Parkinson-White syndrome, but with different physical parameters used during ablation. The protocol used in this series has been shown to be safe in patients with resistant flutters.24 This is probably because the power was limited to 50 W, with a mean delivered power of ∼40 W (a frequently reached power with conventional catheter), in fact resulting in a lower total estimated delivered energy. It is also important to note that great care was taken to stay away from the septal isthmus and the coronary sinus because in this region, the proximity of the AV conduction system and thin-walled coronary veins increases the risk of damage to these structures.

Limitations

It is possible that some patients would have had a successful outcome with additional applications with the conventional catheter without requiring a crossover. However, this is of limited consequence for the study, because only 4 patients crossed over.

Conclusions

The primary use of irrigated-tip catheters allows safe, efficient, and rapid ablation of the cavo-tricuspid isthmus for the treatment of common flutter.

References


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