Prospective randomised comparison of irrigated-tip and large-tip catheter ablation of cavotricuspid isthmus-dependent atrial flutter

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Background Radiofrequency (RF) ablation of cavotricuspid isthmus (CTI) dependent flutter can be performed using different types of ablation catheters. It has been proposed that irrigated and large-tip catheters are capable of creating larger lesions, resulting in greater efficacy. This prospective, randomised clinical study compared the efficacy of irrigated and large-tip catheters of different designs.

Methods Eighty patients (69 men, 66 ± 11 years) undergoing de novo RF ablation of CTI-dependent flutter were randomised to ablation using one of the following catheters: (i) externally-irrigated (n = 20), (ii) internally-cooled (n = 20), (iii) single sensor, 8-mm tip (n = 20), or (iv) double sensor, 8-mm tip (n = 20). The study endpoint was the demonstration of bidirectional CTI conduction block within 12 min of cumulative RF delivery. Crossover to the externally-irrigated catheter was permitted if this was not achieved. The ablation and procedural parameters, safety and efficacy were compared.

Results The primary endpoint was achieved in 64 patients (80%), including all 20 patients randomised to the externally-irrigated catheter. Crossover was required in 16 patients: 9 initially using the internally-cooled-tip (45%), 3 using single-sensor, 8-mm-tip (15%), and 4 using double-sensor, 8-mm-tip (20%) catheters. The higher initial failure rate with the internally-cooled-tip catheter was significant compared to the externally-irrigated (p = 0.001) and single-sensor, 8-mm-tip (p = 0.04) catheters. The externally-irrigated catheter achieved the study endpoint more frequently with fewer RF applications of shorter duration compared to the internally-cooled-tip catheter and 8-mm-tip catheters, the difference being significant compared with internally cooled ablation. No major complications were observed.

Conclusion Among commonly used ablation catheters, the externally-irrigated catheter has a higher efficacy for rapid achievement of CTI block.

Introduction

Radiofrequency (RF) catheter ablation is advocated for the management of drug-resistant cavotricuspid isthmus (CTI) dependent flutter. While bidirectional CTI...
conduction block is effective in preventing episodes of atrial flutter,\textsuperscript{1–7} it may be difficult to achieve in some patients. Post mortem and imaging studies have demonstrated that this region may have complex and varied anatomy, with pouches, recesses, trabeculations, irregularities, and varied muscle thickness, all potential impediments for ablation.\textsuperscript{8–11}

Various catheter technologies have evolved to improve procedural success. Irrigated or large-tip catheters have the theoretic advantage of creating wider and deeper lesions than the conventional catheters.\textsuperscript{12,13} The superior clinical efficacy of these catheters compared to the conventional 4-mm catheters for flutter ablation has been confirmed by several studies.\textsuperscript{13–19}

However, these technologies have varied catheter designs, ranging from different forms of irrigation (external or internal irrigation) to the incorporation of sensors with the 8-mm-tip catheters (single or double sensors). This prospective, randomised clinical study was designed to compare the efficacy of four commercially available catheters, each with one of the properties listed above, for the ablation of CTI-dependent atrial flutter.

Methods

Study population

The study comprised 80 consecutive patients (69 males, 66 ± 11 years) undergoing de novo RF ablation of right atrial flutter. The baseline characteristics of these patients are presented in Table 1. CTI-dependent atrial flutter was defined by its characteristic surface electrocardiographic appearance and was confirmed in patients in atrial flutter at the time of ablation by electrophysiologic evaluation using established criteria.\textsuperscript{4}

The study was prospectively designed, requiring 16 patients in each group to demonstrate a 40% reduction in fluoroscopy duration using externally-irrigated ablation, with 80% power.\textsuperscript{16} All patients provided written informed consent.

Electrophysiologic study

All antiarrhythmic drugs, with the exception of amiodarone, were discontinued more than 5 half-lives prior to the procedure. In all cases the procedure was performed under light sedation (midazolam) and analgesia (nalbuphine).

Two catheters were inserted percutaneously via the right femoral vein and positioned under fluoroscopic guidance. The first deflectable quadripolar catheter (X-Trem, ELA-Medical, Montrouge, France) was positioned within the coronary sinus, with the proximal pole at the ostium of the coronary sinus, and was used for pacing and recording. The second catheter was the ablation catheter selected by the study protocol.

The surface electrocardiogram and bipolar endocardial electrograms were continuously monitored and recorded for off-line analysis (Bard Electrophysiology, Lowell, MA, USA). Intracardiac electrograms were filtered from 30–500 Hz and measured at a sweep speed of 100 mm/s. The system was configured to monitor and provide the mean power, temperature, and impedance during each RF application.

Study protocol and radiofrequency ablation

Patients were prospectively randomised to ablation utilising one of the four following ablation catheters and predetermined ablation parameters:

(i) Externally-irrigated tip (5-mm tip, Celsius Thermo-Cool, Biosense Webster, Diamond Bar, CA, USA). Temperature-controlled RF delivery was performed with a maximum power output of 50 W and temperature limit of 50 °C. The catheter was irrigated using 0.9% saline infusion at a flow rate of 20–40 mL/min during RF delivery and 2 mL/min between applications using a commercially available pump (Cool Flow, Biosense Webster).

(ii) Internally-cooled tip (4-mm tip, Chilli, Boston Scientific, Sunnyvale, CA, USA). Temperature-controlled RF delivery was performed with a maximum power output of 50 W and temperature limit of 50 °C. During ablation, glucose 5% was infused internally via an automatic injector system (Medrad Inc., Indianapolis, PA, USA) at 24–36 mL/min as previously recommended.\textsuperscript{20–21}

(iii) Single-sensor 8-mm tip (standard Blazer II XP, EP Technologies Inc, San Jose, CA, USA). Temperature-controlled ablation was performed at a maximum temperature of 60 °C with power limited to 70 W.

(iv) Double-sensor 8-mm tip (Celsius DS, Biosense Webster, Diamond Bar, CA, USA). Temperature-controlled ablation was performed at a maximum temperature of 60 °C with power limited to 70 W.

In each case ablation was performed by point-by-point applications for a maximum duration of 120 seconds each to create

<table>
<thead>
<tr>
<th>Table 1: Patient characteristics</th>
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<tbody>
<tr>
<td></td>
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<tr>
<td>Age (years)</td>
</tr>
<tr>
<td>Male</td>
</tr>
<tr>
<td>Flutter duration (months)</td>
</tr>
<tr>
<td>History of AF</td>
</tr>
<tr>
<td>Failed drugs (no.)</td>
</tr>
<tr>
<td>Amiodarone use</td>
</tr>
<tr>
<td>Structural heart disease</td>
</tr>
<tr>
<td>Heart failure</td>
</tr>
<tr>
<td>LA diameter (mm)</td>
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<tr>
<td>LV end diastolic diam (mm)</td>
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<tr>
<td>LV end systolic diam (mm)</td>
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<tr>
<td>LV ejection fraction (%)</td>
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</table>

AF, atrial fibrillation; LVEF, left ventricular ejection fraction.
Prospective randomised comparison of irrigated-tip and large-tip catheter

Subcutaneous low-molecular-weight heparin was administered defined as the time from skin puncture to removal of catheters. Procedure duration was necessary to achieve catheter stability or to improve the manoeuvrability of the catheter. After 3 RF energy applications or a rise in impedance ≥25 Ω, the catheter was removed to check if clot or char had formed on the electrode.

The endpoint for successful RF ablation was the demonstration of bidirectional isthmus block by previously published criteria.22 The primary endpoint of the study was the achievement of procedural success within 12 min of RF energy applications using the randomised catheter, following which crossover to a nonrandomised catheter was permitted. Patients randomised to the internally-cooled or 8-mm-tip catheters were crossed-over to the externally-irrigated-tip catheter, and those randomised to the externally-irrigated-tip catheter crossed over to the internally-cooled catheter.

The following procedure-related parameters were compared: (i) number and duration of RF applications, (ii) fluoroscopy duration, (iii) procedure duration, (iv) occurrence of impedance rise, (v) formation of clots on the catheter, (vi) procedure-related complications, and (vii) long-term clinical outcome. For the purposes of the study, procedure duration was defined as the time from skin puncture to removal of catheters.

Post-ablation care and follow-up

Subcutaneous low-molecular-weight heparin was administered at prophylactic doses twice daily, commencing 6 h following ablation. Clinical and electrocardiographic reviews were performed daily for 2 days while the patient was still in the hospital to determine recurrence of arrhythmia or complications. Following ablation, all antiarrhythmic medication was discontinued in the absence of concurrent indications. Follow-up reviews were performed by the referring physician and information about further events was obtained by telephone interviews.

Statistical analysis

All continuous variables are reported as mean ± SD. The normality of distribution for each variable was ascertained with the Shapiro-Wilk test before comparison by analysis of variance (ANOVA) to determine if there were significant differences between mean values in each group. If the overall test (F test) for a variable was significant, post hoc pairwise comparisons were made with Tukey’s HSD test for all possible combinations. Categorical data are presented as numbers (percentages) and compared using the χ² test, with Fisher’s exact test as appropriate. Analysis was based on intention-to-treat. Statistical significance was established as p < 0.05.

Results

Eighty patients were prospectively randomised into four equal groups. There were no significant differences in baseline clinical or echocardiographic characteristics between groups (Table 1).

Procedural endpoint

Ablation was commenced during atrial flutter in 52 patients (65%) and during pacing from the proximal coronary sinus in 28 patients (35%). There was no significant difference between groups in the rhythm at the start of the procedure.

There was a significant difference between the catheters used to achieve the primary endpoint of bidirectional CTI block within 12 min of RF (p = 0.004). This endpoint was achieved in 64 patients (80%): 20 (100%) with the externally-irrigated catheter, 11 (55%) with the internally-cooled catheter, 17 (85%) with the single-sensor, 8-mm-tip catheter, and 16 (80%) with the double-sensor, 8-mm-tip catheter (Table 2). The differences were statistically significant for the following comparisons: externally irrigated versus internally cooled (p = 0.001) and internally cooled versus 8-mm single sensor (p = 0.04). There was no significant difference in achievement of the primary study endpoint between the two 8-mm-tip catheters studied (p = 1.0).

Crossover to a nonrandomised catheter for an additional 8.1 ± 6.4 min of RF delivery was required in 16

### Table 2. Procedural parameters

<table>
<thead>
<tr>
<th></th>
<th>Externally irrigated (n = 20)</th>
<th>Internally cooled (n = 20)</th>
<th>8-mm single sensor (n = 20)</th>
<th>8-mm double sensor (n = 20)</th>
<th>Overall p-value (F test)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ablation started during flutter</td>
<td>13 (65%)</td>
<td>15 (75%)</td>
<td>11 (55%)</td>
<td>13 (65%)</td>
<td>0.62</td>
</tr>
<tr>
<td>Failure to achieve endpoint</td>
<td>0</td>
<td>9 (45%)</td>
<td>3 (15%)</td>
<td>4 (20%)</td>
<td>0.004</td>
</tr>
<tr>
<td>Number of RF applications</td>
<td>6 ± 4</td>
<td>11 ± 6</td>
<td>9 ± 5</td>
<td>8 ± 6</td>
<td>0.02</td>
</tr>
<tr>
<td>RF duration (min)</td>
<td>8.3 ± 4.5</td>
<td>13.1 ± 7.9</td>
<td>11.5 ± 7.2</td>
<td>13.3 ± 10.4</td>
<td>0.045</td>
</tr>
<tr>
<td>Crossover</td>
<td>0</td>
<td>9 (45%)</td>
<td>3 (15%)</td>
<td>4 (20%)</td>
<td>0.004</td>
</tr>
<tr>
<td>Fluoroscopy duration (min)</td>
<td>6.8 ± 4.3</td>
<td>12.9 ± 6.0</td>
<td>9.9 ± 6.8</td>
<td>12.9 ± 10.3</td>
<td>0.02</td>
</tr>
<tr>
<td>Procedure duration (min)</td>
<td>38 ± 16</td>
<td>47 ± 21</td>
<td>37 ± 16</td>
<td>45 ± 24</td>
<td>0.20</td>
</tr>
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</table>

Post-hoc comparison of variables with significant overall p-values

<table>
<thead>
<tr>
<th></th>
<th>Ext vs. Int</th>
<th>Ext vs. SS</th>
<th>Ext vs. DS</th>
<th>Int vs. SS</th>
<th>Int vs. DS</th>
<th>SS vs. DS</th>
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</thead>
<tbody>
<tr>
<td>Failure to achieve endpoint</td>
<td>0.001</td>
<td>0.23</td>
<td>0.11</td>
<td>0.04</td>
<td>0.09</td>
<td>1.0</td>
</tr>
<tr>
<td>Number of RF applications</td>
<td>0.008</td>
<td>0.18</td>
<td>0.41</td>
<td>0.61</td>
<td>0.32</td>
<td>0.96</td>
</tr>
<tr>
<td>RF duration</td>
<td>0.047</td>
<td>0.50</td>
<td>0.10</td>
<td>0.60</td>
<td>0.99</td>
<td>0.80</td>
</tr>
<tr>
<td>Crossover</td>
<td>0.001</td>
<td>0.23</td>
<td>0.11</td>
<td>0.04</td>
<td>0.09</td>
<td>1.0</td>
</tr>
<tr>
<td>Fluoroscopy duration</td>
<td>0.04</td>
<td>0.53</td>
<td>0.04</td>
<td>0.52</td>
<td>1.0</td>
<td>0.54</td>
</tr>
</tbody>
</table>

Ext, externally-irrigated catheter; Int, Internally-cooled catheter; SS, 8-mm-sensor catheter; DS, 8-mm double-sensor catheter.
patients: 9 (45%) randomised to the internally-cooled catheter, 3 (15%) randomised to the single-sensor, 8-mm-tip catheter, 4 (20%) randomised to the double-sensor, 8-mm-tip catheter, and none of the patients randomised to the externally-irrigated catheter ($p = 0.004$).

**Procedural parameters**

The procedural characteristics for the four study catheters are presented in Table 2. The externally-irrigated catheter achieved bidirectional block using fewer RF applications and a shorter RF duration compared to the internally-cooled catheter or either of the 8-mm-tip catheters; this was significant compared with the internally-cooled catheter ($p = 0.008$ and $p = 0.05$, respectively).

Fluoroscopy duration was shorter for the externally-irrigated catheter compared to the internally-cooled and 8-mm, double-sensor catheters ($p = 0.04$ for both). There was also a trend toward shorter procedural duration utilising either the externally-irrigated or the single-sensor, 8-mm-tip catheter compared to the others.

The physical characteristics of RF application for each catheter evaluated are presented in Table 3. The handling characteristics of the internally-cooled catheter was such that in 5 (25%) patients a long sheath was required to improve catheter stability or manoeuvrability, significantly more than with the externally-irrigated or double-sensor, 8-mm-tip catheters ($p = 0.047$ for both). With these latter catheters, stability during ablation was achieved without the use of a long sheath in all cases.

The mean power, temperature, and impedance achieved during each ablation demonstrated a clear dichotomy between the irrigated and 8-mm-tip catheters, with the irrigated-tip catheters demonstrating lower power and temperature and higher impedance during ablation. There was no difference in these parameters between the internally-cooled and externally-irrigated catheters, or the single- and double-sensor, 8-mm-tip catheters.

Impedance rise interrupting RF energy delivery was observed more frequently with the internally-cooled (55% of cases) and single-sensor, 8-mm-tip catheters (35% of cases); this was significantly more than with the externally-irrigated ($p = 0.006$ vs. internally-cooled) or the double-sensor, 8-mm-tip catheter ($p = 0.001$ vs. internally-cooled and $p = 0.04$ vs. single-sensor, 8-mm tip).

In the current series there was a low incidence of coagulum or char formation on the catheter, with no significant difference between catheters. Additionally the "pop phenomenon" was observed in 2 patients with the externally-irrigated and 3 patients with the internally-cooled catheters compared to none with the 8-mm-tip catheters (irrigated ablation versus 8-mm-tip ablation, $p = 0.06$).

**Procedural complications and follow-up**

There were no major procedural complications. Four patients developed localised groin complications (haematoma or arteriovenous fistula) that were managed conservatively.

During a median follow-up of 15 months (range 5–21), 78 patients were free of recurrence. Both patients in whom arrhythmia recurred had been initially randomised and ablated using the internally-cooled catheter. Ablation was subsequently repeated successfully.

**Discussion**

This prospective randomised study provides new information pertaining to the choice of catheters used for ablation in CTI-dependent atrial flutter. It demonstrates that the externally-irrigated catheter provides the advantage of greater procedural success using shorter RF...
energy application and fluoroscopy durations compared with the other catheters.

Radiofrequency catheter ablation has been demonstrated to be highly effective in the cure of CTI-dependent atrial flutter in about 80–90% of the patients. The complex and variable anatomy of the CTI can, however, be an impediment to the successful achievement of bidirectional isthmus conduction block resulting in procedural failures or recurrence of arrhythmia. Different strategies have been proposed to overcome resistant cases. Of note, the irrigated catheter utilised both types of catheters are now available commercially in various designs. Of note, the irrigated catheter utilised in previously published series had an internally-cooled tip design. However, both types of catheters are now available commercially in various designs. Of note, the irrigated catheter utilised in previously published series had an internally-cooled tip design. However, both types of catheters are now available commercially in various designs. Of note, the irrigated catheter utilised in previously published series had an internally-cooled tip design.

Comparison of irrigation designs

In this study, the externally-irrigated design was shown to have superior efficacy to the internally-cooled design, requiring significantly shorter RF application, fluoroscopy, and procedural duration to achieve bidirectional CTI conduction block. In addition, while both patients with clinical recurrence were ablated using the internally-cooled design, none of the patients treated with the externally-irrigated catheter had clinical recurrence.

These differences between the procedural and clinical outcome may be explained in part by the size of the lesions produced with the different electrode designs. Indeed, a recently published in vitro comparison reported different efficacies associated with different irrigated electrode designs, with the externally-irrigated electrode creating larger lesions than the internally-cooled using the same irrigation rates. Another factor contributing to these different results may be the handling properties of the catheters during the ablation procedure. The relative stiffness of the externally-irrigated catheter facilitated positioning and stability on the isthmus during ablation and optimised catheter contact pressure, creating larger and deeper lesions during ablation. In contrast, the internally irrigated catheter softened after insertion into the body due to warming, resulting in reduced manoeuvrability and stability. As a result, a long sheath for stabilisation was required in 25% of cases using the internally-cooled tip catheter, perhaps reflecting the inherent differences in design of these catheters.

In the externally-irrigated catheter, the irrigant spreads radially from the tip through 6 irrigation ducts 0.4 mm in diameter, yielding relatively high electrode surface flow, especially near the irrigation holes. In contrast, the internally-cooled catheter has no flow around the electrode surface. It has been suggested that electrode surface flow could determine lesion size by preventing electrode-endocardial interface boiling and reducing coagulum and char formation.

The physical characteristics of the electrodes and catheters may also influence the ablation profile. The internally-cooled tip design has been reported to be prone to impedance rises, curtailing the duration of RF application. The findings of the current study confirm these prior observations, with 55% of the cases randomised to the internally-cooled tip catheter experiencing at least one interruption of RF delivery due to an impedance rise, significantly more than with the externally-irrigated catheter.

These factors may all potentially contribute to the differences observed in the current study between the two designs of irrigated-tip ablation catheters.

Differences between irrigated and large-tip catheters

Compared to both 8-mm-tip catheters, the externally-irrigated catheter showed a trend toward fewer RF applications and a shorter duration of RF and fluoroscopy (significant versus the 8-mm, double-sensor catheter) to achieve CTI block. This difference could again be partly explained by the larger lesions created by the externally-irrigated catheter. In addition, while the power delivered by irrigated catheters was lower, reflecting the pre-determined ablation parameters, they were subject to less variation during RF energy delivery than the 8-mm-tip catheters. With a conventional electrode, in the presence of low local convective cooling, the elevation of electrode temperature dramatically reduces the power delivered and, therefore, the size of the lesions. This effect could be ameliorated by increasing the electrode size. However, it is possible that a larger electrode design may have resulted in nonuniform heating and tissue contact. Irrigation of the electrode dissociates the power delivered by local convective cooling and results in a nearly constant and stable power delivery for each application, as confirmed by our results.

However, as observed in previously published studies, the internally-cooled-tip catheter has not been found to be superior to the 8-mm-tip catheters. Indeed, in the current study, the study endpoint was achieved more frequently using the single-sensor, 8-mm-tip catheter than the internally-cooled-tip catheter. Although the latter catheter delivered power uniformly, its handling characteristics and susceptibility to impedance rises may have affected the result.

The 8-mm-tip electrode containing 2 thermocouple sensors was expected to provide more accurate information about temperature along the length of the catheter tip and thus avoid high temperatures. While this technology resulted in fewer episodes of impedance rise compared to the single-sensor, 8-mm-tip catheter (1 versus 7 episodes), the double-sensor design was associated with lower power delivery. This may be partly due to the more homogenous temperature measurement provided by the 2 thermocouples and resulted in no
The primary study endpoint requiring achievement of complete CTI block was usually achieved with the externally-irrigated-tip catheter, where we selected this time frame based on our previous experience. Cooling of the catheters as well. Therefore, a long sheath was used only when there were significant problems with positioning and stability.

**Conclusion**

While irrigated and large-tip catheters have proven efficacy in the ablation of atrial flutter, this study demonstrates that this efficacy is further affected by electrode design and the physical properties of the individual catheters. The externally-irrigated catheter has a higher efficacy for rapid achievement of CTI block compared to internally-cooled ablation. However, within the limits of the current study design there was no statistical difference between the externally-irrigated catheter and the single-sensor, 8-mm-tip catheter.

**Acknowledgements**

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