Primary closed cooled tip ablation of typical atrial flutter in comparison to conventional radiofrequency ablation

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The purpose of this prospective, non-randomized study was to investigate the effectiveness of cooled radiofrequency ablation (cRFA) compared with conventional radiofrequency application (RFA) for ablation of typical atrial flutter (AF).

Methods Isthmus ablation was carried out using a system with a circulating fluid path through the ablation tip to control tip temperature in 100 patients with AF. Thirty consecutive AF patients underwent conventional RFA. The number of applications for cRFA was 13.7 ± 6.9 and for RFA 24.0 ± 14.5 (P < 0.0007) at powers between 35 and 50 W and a tip temperature range of 38-43°C. Ablation duration and fluoroscopy time were 9.9 ± 4.9 and 22.8 ± 10.7 min for cRFA, respectively. In contrast, for RFA, ablation duration and fluoroscopy time were 20.6 ± 14.2 (P < 0.0001) and 27.4 ± 12.7 min, respectively. In 93% of the cooled tip group and in 80% of the control group bidirectional block was confirmed.

At 6-months follow-up, recurrence rates were 9 in the cooled-tip group and 7 in the control group, corresponding to 10.4% and 25.9%. There were no significant complications. Compared with RFA, cRFA requires lower application numbers. Recurrence rates are low and the overall success rate is high.

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Key Words: Radiofrequency ablation, closed cooled ablation, typical atrial flutter.

Introduction

Radiofrequency (RF) ablation in the isthmus area between the tricuspid valve and the inferior vena caval orifice with the endpoint of creation of bi-directional block has become standard therapy for curative treatment of typical atrial flutter[1–8]. However, there is a group of patients in whom ablation is difficult to perform or who are resistant to conventional RF ablation. Causes of unsuccessful RF ablation may be, apart from inaccurate localization of the target site for ablation, gaps in the lesion line and lesions of inadequate width or depth that can also develop from post-ablation tissue recovery. Long-term recurrence rates vary between 5% and 30%[9–18]. Atypical anatomical conditions may result in increased numbers of RF applications and prolonged ablation duration with increased risk of healthy tissue damage or clot formation.

RF ablation using methods to cool the ablation tip is expected to be more appropriate for the creation of long and deep linear lesions. There are two types of cooled RF catheters: (1) catheters with lumens, which infuse saline through the tip directly onto myocardium, and (2) catheters with an internal circulation path to pass saline into and out of the tip. For conventional RF ablation, temperature values at the catheter tip are typically controlled in the range 60–70°C, while for cooled RF ablation these target values are markedly lower, due to the tip cooling process. Hence cooling the catheter tip allows greater energy delivery and moves the centre of maximal heating deeper into myocardium, thereby creating larger and deeper lesions. Furthermore, bubble formation (popping) occurs only sporadically until high power levels are applied, while impedance rises are usually not associated with clot formation at the catheter tip[19–31].

Both types of catheters have been clinically tested for ablation of ventricular tachycardias and have been recently used safely and with high success rates for
ablation of typical atrial flutter\cite{32-42}. This study sought to prove that isthmus ablation is feasible and safe using the internal circulation method for tip cooling. Furthermore, attention was given to the number of applications and ablation duration.

**Patients and methods**

A series of 130 consecutive procedures for curative treatment of typical atrial flutter were performed from December 1998 to March 2000. The inclusion criteria for this single-centre, prospective study included: a history of two or more episodes of recurrent symptomatic typical atrial flutter with at least one episode documented and eligibility for ablation treatment. Exclusion criteria were any of the following conditions: pregnancy, less than 18 years of age, history of deep vein thrombosis or pulmonary emboli, contraindication to heparin, right atrial mass (tumour or thrombus), prosthetic tricuspid valve, complex congenital heart disease involving right atrial structures, or significant pericardial effusion. Pre-procedure transthoracic echo was performed in all patients. Initially, thirty consecutive patients were ablated with conventional 8 mm-tip (2 × 4 mm) catheter (Cerablate, Dr Osypka GmbH, Rheinfelden-Herten, Germany or Cosio Flutter, Medtronic Inc, Minneapolis, MN, U.S.A.). This group represented the control group. Following completion of the control group, 100 consecutive patients were ablated using cooled RF ablation. This cohort contained only patients that were treated by methods using internal circulation of tip cooling.

For all 100 patients the ‘Chilli’ Cooled Ablation System was used (Cardiac Pathways Corp., Sunnyvale, CA, U.S.A.). It consists of a RF generator and pump system (Model 8004), a deflectable mapping and ablation catheter, cables and tubes that connect the catheter to the generator and the pump. The 7F quadrapolar ablation catheter has two cooling lumens through which saline solution at room temperature is circulated through the tip under a constant volumetric flow rate of 0.6 ml/s using the injector pump. Temperature of the 4 mm long catheter tip is monitored with a thermocouple embedded just proximal to the inside edge of the tip (Fig. 1).

Furthermore, the system provides continuous digital and/or graphical display of system power, impedance, current, voltage and tip temperature. The generator has controls for power, application duration, temperature and impedance. It can produce up to 50 W of power. The values for maximum impedance and single application duration were set to 200 Ω and 60 s respectively in

![Cooled Ablation Catheter](image)

**Figure 1** Measurements (upper panel) and cross section (lower panel) of the steerable, 8F and 4 mm-tip ablation catheter. The cooling tubes are connected to the fluid ports of the shaft of the catheter.
The cooled-tip system. During ablation power was increased stepwise manually to a maximum value between 35 and 50 W to achieve a target temperature in the range of 38–43°C. RF energy application was manually discontinued in the event of sudden impedance rise or temperatures above about 45°C. During application of energy the catheter was not moved.

The conventional temperature-controlled RF ablation was performed using an Osypka HAT 300 Smart (Dr Osypka GmbH, Rheinfeld-Herten, Germany) RF generator. The selected tip temperature was 60°C at 70 W maximum power.

All patients (cooled-tip and conventional RF-ablation) received ACT-controlled intravenous heparin. The target ACT level was 150 to 200 s. A 7F duodecapolar Halo catheter and the 7F quadrapolar ablation catheter were inserted via the femoral vein. A 6F decapolar CS-catheter was inserted via the left cubital or subclavian vein in all patients. Patients with atrial fibrillation received electrical cardioversion immediately before the procedure so that they were converted to typical atrial flutter or sinus rhythm. In patients with sinus rhythm the procedure started by obtaining proof of bi-directional conduction. In both groups a series of RF applications was applied on the posteroseptal isthmus between the tricuspid valve annulus and the inferior vena caval orifice. Twenty-three patients had structural heart disease (heart disease due to hypertension 13, dilated cardiomyopathy 2, coronary artery disease 8, valvular disease 2, chronic heart failure 5) in the cooled-tip group and 10 patients in the control group (coronary artery disease 7, valvular disease 1, dilated cardiomyopathy 2). Table 1 summarizes the clinical characteristics of the patients.

In all patients bi-directional block was confirmed by complete clockwise isthmus block during proximal coronary sinus pacing and counter-clockwise isthmus block during low lateral right atrial pacing. Post-ablation care included ECG monitoring and transthoracic echo, and patients receiving subclavian punctures were X-rayed. Only patients with histories of atrial fibrillation received a recommendation of antiarrhythmic drugs. All patients received 100 to 300 mg aspirin for 4 weeks. At 6-months follow-up, a clinic visit including surface- and Holter-ECG was performed in all patients.

### Statistical analysis

For all samples mean value and standard deviation are given. The base-line comparisons between the treatment groups were performed for continuous values with t-test (unpaired, two-tailed) and with chi-square test for classical variables. To compare the efficacy of the ablation procedures, $P$-values for all parameters were calculated. The null-hypothesis was: there is no difference between the ablation techniques. A two-tailed t-test for continuous values with unpaired samples and chi-square test for classified variables was used. Completer-analysis was performed for all variables. The $P$-value was calculated. Because of the explorative character of the study, an a-adjustment was not performed. A $P$-value of less than 0.05 was considered to indicate statistical significance. A linear, multivariate regression analysis of the number of applications per patient in sequential order was performed to demonstrate/exclude a bias due to the learning effect.

### Results

There were no significant differences in the clinical characteristics of the examined patient groups regarding gender, age, duration of AF, LA size, ejection fraction, history of atrial fibrillation, heart disease and previous heart surgery (Table 1). In the cooled RF group, ablation was performed in 56 cases during sinus rhythm and in 44 cases during typical atrial flutter. Prior to ablation 7 patients received electrical cardioversion to sinus rhythm (5 patients with atrial fibrillation, 2 patients with atrial flutter), in another 3 patients with atrial flutter overdrive stimulation was carried out.

In the control group, 17 patients had sinus rhythm and 13 patients typical atrial flutter at the beginning of

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Table 1 Clinical characteristics

<table>
<thead>
<tr>
<th></th>
<th>Cooled-tip ablation</th>
<th>Control group</th>
<th>$P$-value</th>
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<tbody>
<tr>
<td>Number of patients</td>
<td>100</td>
<td>30</td>
<td></td>
</tr>
<tr>
<td>Gender [male/female]</td>
<td>76/24</td>
<td>25/5</td>
<td>0.36</td>
</tr>
<tr>
<td>Age [years]</td>
<td>63.8 ± 6.9 (32–81)</td>
<td>61.9 ± 10.9 (38–82)</td>
<td>0.35</td>
</tr>
<tr>
<td>Duration of typical atrial flutter [years]</td>
<td>1.4 ± 3.1 (0.5–6)</td>
<td>2.1 ± 1.4 (0.17–6)</td>
<td>0.32</td>
</tr>
<tr>
<td>Left atrial size [mm]</td>
<td>42.4 ± 6.2 (29–57)</td>
<td>42.6 ± 4.7 (33–52)</td>
<td>0.89</td>
</tr>
<tr>
<td>Left ventricular ejection fraction [%]</td>
<td>56.9 ± 10.8 (25–75)</td>
<td>55.2 ± 13.6 (25–70)</td>
<td>0.29</td>
</tr>
<tr>
<td>History of atrial fibrillation</td>
<td>19 (19%)</td>
<td>5 (16.6%)</td>
<td>0.77</td>
</tr>
<tr>
<td>Structural heart disease</td>
<td>37 (37%)</td>
<td>10 (33.3%)</td>
<td>0.71</td>
</tr>
<tr>
<td>Previous heart surgery</td>
<td>13 (13%)</td>
<td>5 (16.6%)</td>
<td>0.61</td>
</tr>
</tbody>
</table>

There were no significant differences between the two studied groups, therefore comparability can be inferred. Data are depicted as mean ± SD (max–min).
the ablation. In 2 patients cardioversion was necessary to terminate periprocedural atrial fibrillation.

In the cooled RF ablation group, complete bi-directional block was achieved in 93 patients (93%); unidirectional block in 5 patients (5%) and no block in 2 patients (2%). In the control group 24 patients (80%; \( P=\text{ns vs cooled RF group} \) had bi-directional block, 1 unidirectional block (3.3%) and 5 patients (16.6%) had no block, but only delayed conduction after ablation.

Following the procedure and at hospital discharge all patients were in sinus rhythm. Table 2 summarizes the ablation data in the 2-patient groups. Since it always takes some seconds until maximum power delivery, short energy applications are possibly not efficacious. Only data on sufficient energy applications of at least 5 s duration (cooled RF and conventional ablation) are taken into account.

The number of applications necessary to create bi-directional block, total ablation duration and total procedure time and also total energy were significantly reduced with the cooled RF system. There were no significant differences in fluoroscopy times between the two groups.

Follow-up data were available for 87/100 patients in the cooled RF group and of 27/30 patients in the control group. Table 3 shows the 6-months follow-up data of all patients.

The recurrence rate at 6 months was markedly higher in the control group (10.4% vs 25.9%; \( P=0.04 \)). All patients (7) with recurrent typical atrial flutter in the control group were successfully reablated with the cooled-tip system. Additionally, bi-directional block was achieved in 5 patients in the cooled-tip group in a second session. Two patients with recurrence in the cooled group had successful conventional ablation in a second session. Betablockers or antiarrhythmic drugs (mostly sotalol) were given to all patients with paroxysmal atrial fibrillation or chronic heart failure/coronary artery disease. No other patients were on antiarrhythmic drugs.

In the cooled RF group sinus bradycardia was observed in 3 patients and 1st degree AV block in 1 patient after ablation, while another patient had 2nd degree AV block (type I) not related to the ablation. In 4 patients pacemakers were implanted due to binodal disease (2 patients) and sinus node syndrome (2 patients). One patient after cooled RF ablation showed a small post-procedure pericardial effusion, which did not require surgical or medical intervention. In the control group pacemaker implantation was necessary in 3 patients due to binodal disease after ablation of atrial flutter. There were no procedure related severe complications or adverse events.

### Discussion

Our study clearly demonstrates an advantage of the cooled RF ablation technique compared with conventional radiofrequency energy in the treatment of typical atrial flutter. As there were no significant differences between the examined groups in any of the parameters measured at the start of the study, comparability of the two patient groups can be assumed. Cooled RF ablation significantly reduced the number of applications creating bi-directional isthmus block as well as ablation duration and procedure time. Cooled RF ablation also increased efficacy of primary ablations and significantly reduced the recurrence rate without

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**Table 2** Ablation procedure details. Energy settings were continuously varied manually between 35–50 W to reach the target temperature of 40°C. Both procedure and ablation duration and total energy were significantly reduced with the cooled-system

<table>
<thead>
<tr>
<th></th>
<th>Cooled-tip ablation (n=100)</th>
<th>Control group (n=30)</th>
<th>( P )-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of sufficient energy applications*</td>
<td>13·7 ± 6·9 (1–36)</td>
<td>24·0 ± 14·5 (5–56)</td>
<td>&lt;0·0007</td>
</tr>
<tr>
<td>Total ablation duration [min]</td>
<td>9·9 ± 4·9 (1–23·7)</td>
<td>20·6 ± 14·2 (3–4·571)</td>
<td>&lt;0·0001</td>
</tr>
<tr>
<td>Fluoroscopy time [min]</td>
<td>22·8 ± 10·7 (8–59)</td>
<td>27·4 ± 12·7 (7·9–52·0)</td>
<td>0·0673</td>
</tr>
<tr>
<td>Total procedure time [min]</td>
<td>72·7 ± 26·9 (30–180)</td>
<td>122·7 ± 42·8 (40–180)</td>
<td>&lt;0·0001</td>
</tr>
<tr>
<td>Total energy used p.p. [W]</td>
<td>25843·9 ± 14406·1 (1196–66756)</td>
<td>39370·5 ± 24348·5 (4780·8–99548·0)</td>
<td>0·0003</td>
</tr>
<tr>
<td>Maximum power [W]</td>
<td>35–50</td>
<td>70 W</td>
<td></td>
</tr>
<tr>
<td>Tip temperature [°C]</td>
<td>38–43</td>
<td>60°C</td>
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*=Sufficient energy application: application duration ≥ 5 s (cooled-tip and without cooling); p.p.=per procedure; ‡=temperature controlled. Data are depicted as mean ± SD (max–min).
increasing the risk of the procedure. At 6-months follow-up, 24.1% in the cooled RF group and 14.8% in the control group exhibited atrial fibrillation or atypical atrial flutter corresponding with published data of others\(^9,13–15\) \((P=\text{ns})\). Fluoroscopy time was prominently reduced in the cooled-tip group but the difference did not reach the significance. This is possible due to the longer application durations with the cooled system (target duration: 60 s). The ‘Chilli’ Cooled Ablation System does not allow the display of the intracardiac EGM from the distal electrode during ablation. This makes frequent X-ray controls of the catheter position necessary.

Cooling the ablation electrode maintains the electrode-tissue interface at low temperature and prevents impedance rise due to clot formation allowing greater RF power delivery and thus creating larger and deeper lesions. This could be the reason for the beneficial effect on the ablation procedure and on the recurrence rate. Since the centre of maximal heating is deeper in the myocardium for cooled ablation and temperature is measured at the catheter tip, the meaning of (direct) temperature measurement is lost. As a corollary of the potential of delivering high power over longer time intervals, there was concern that e.g. unwanted tissue damage or even perforations might occur. Therefore, the safety of this new tool in specific ablations is of paramount interest. The study also confirms that cooled ablation using the ‘Chilli’ ablation catheter is safe, even in the ablation of the human cavotricuspid isthmus. Clot or char formation were not observed, despite rare sudden impedance rise as a result of catheter instability or insufficient contact. As demonstrated in animal and clinical studies, the risk of coronary and myocardial injury is minimized by restricting the maximum power delivered to 50 W and by setting the maximum temperature to 40°C\(^{25–29}\). Our study confirmed these suggestions. The generator allows pre-setting the maximum power to 50 W over 2 min, but power delivery never exceeded 60 s. Mean power of about 42 W and application duration per procedure of about 50 s respectively were slightly above the range of conventional RF ablation. Hence, cooling the catheter tip provides protection against thromboembolism. Four patients in the cooled RF group and 3 patients in the control group received permanent dual-chamber pacemakers after the procedure, due to preexisting bidirectional disease or sick sinus syndrome, not related to the ablation. Also the two cases of low-degree AV-block in the cooled RF group were not related to the ablation. One case of pericardial effusion without haemodynamic deterioration was the single procedure related complication in this series, however it may be not necessarily be related to the cooled ablation.

In summary, the use of internal circulating fluid to cool the ablation tip reduces procedure time, ablation duration, fluoroscopy time and recurrence rates without increasing risk.

**Limitations of the study**

The major limitation of the study is the non-randomized character of the patient selection. Only further randomized studies (cooled RF vs non-cooled RF methods) could estimate the real performance of this new ablation tool. A learning curve of the operators could also have possibly affected the results, although the ablations with the cooled RF system were performed after a large number of conventional ablations. Despite this, there is a weak decremental tendency in the number of ablations per patient in the conventional catheter group. However, this tendency did not reach statistical significance in the examined groups \((P=0.349, r=0.095\) in the cooled tip group and \(P=0.155, r=0.266\) in the conventional catheter group, Fig. 2). Therefore, a significant learning effect can be excluded in both groups.
References


