HIGH INCIDENCE OF STEAM POP FORMATION WITH THERAPY COOL FLEX RF ABLATION CATHETER

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Bernard ABI SALEH3

INTRODUCTION

Radiofrequency (RF) catheter ablation is the therapy of choice for several cardiac arrhythmias. The aim of this technique is the creation of myocardial lesions of predictable size, thus minimizing the risk of complications [1].

Lesion size depends on the power delivered to the tissue and to the contact force applied by the catheter, but this is limited by the risk of local thrombus formation. The development of thrombi is directly related to the temperature reached at the catheter tip during the application of RF. Various cooling catheter tip systems have been developed to prevent the occurrence of local thrombus formation, allowing greater power delivery and, as a result, improving catheter efficiency and safety in lesion creation [2].

The two available methods for active electrode cooling to date are internal and external irrigation of the tip, the latter also called open irrigation. With the external system, fluid actively flows through holes arranged on the surface of the distal part of the electrode, reducing the overheating of the tissue-electrode interface [3]. As compared with standard RF ablation catheters, active electrode cooling allows the creation of larger lesions at sites with reduced blood flow and affords a lower incidence of thrombus formation [4].

In recent years a number of different electrode architectures for open-irrigated catheters have been developed, varying the tip dimensions, temperature sensors location and the number, size or distribution of the irrigation ports on the tip surface. However, there are limited data about whether electrode architecture differences have an impact on lesion generation and the occurrence of adverse events.

The aim of this analysis is to compare the safety of the diffuse irrigation of the Cool Flex catheter (Cool Flex catheter; St. Jude Medical) to the ThermoCool catheter (ThermoCool; Biosense Webster, Diamond Bur) that has six distal irrigation channels.

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METHODS

We retrospectively looked at patients that underwent irrigated RF ablation procedures at the American University of Beirut Medical Center (AUBMC) between July 2012 and October 2013. The study was approved by the Institutional Review board of AUBMC and complied with the Declaration of Helsinki. The patient population was divided into two groups depending on the type of catheter used during the procedure: Therapy™ Cool Flex™ RF ablation catheter (Group 1) versus the ThermoCool Celsius® RF ablation catheter (Group 2).

RF energy using Therapy™ Cool Flex™ RF ablation catheter

In group 1, RF energy was delivered with the 4 mm tip fully irrigated Therapy™ Cool Flex™ RF ablation catheter (St Jude Medical, Sylmar, CA).

The catheter is open-irrigated with an irrigation flow at 17 cc per minute during RF energy application, the power delivered was between 15 watts and 30 watts with maximum temperature set at 40 degrees. RF delivery was interrupted in case of sudden rise in impedance.

RF energy using ThermoCool Celsius® RF ablation catheter

In group 2, RF energy was delivered with the 3.5 mm tip with six distal irrigation channels ThermoCool Celsius® RF ablation catheter (Biosense Webster, Waterloo, Belgium).

The catheter is open-irrigated with an irrigation flow at 30 cc per minute during RF energy application, the power delivered was between 20 watts and 40 watts with maximum temperature set at 42 degrees. RF delivery was interrupted in case of sudden rise in impedance.

Endpoints

The primary endpoints were:
1) Steam pop formation (detected by audible cue) &
2) Pericardial effusion by intracardiac and transthoracic echocardiograms.

Follow-up

All patients were monitored overnight on a telemetry unit after the procedure. Patients were followed in the outpatient clinic at 6 weeks post-ablation.

Statistical Analysis

Data distributions were first assessed for normality and for aberrancies.

Numerical data were expressed as mean ± standard deviation, and compared using the Student’s t test (normal distribution) or Wilcoxon test (skewed data).

Categorical data were expressed as percentage and frequency, and compared using the Pearson chi-square test.

A binary logistic regression analysis model was performed looking at predictors of poor outcomes. Because of limited number of events, a composite endpoint of failed procedure, steam pop formation, pericardial effusion, tamponade or death was used. Baseline covariates that were significantly different in the patients characteristics tables or thought to be clinically relevant were entered into the model. A multivariate model was performed adjusting for all univariates with p values < 0.10.

All tests were 2-tailed, and a p value < 0.05 (set a priori) was considered statistically significant. All statistical analyses were carried out with SPSS Statistics version 22 (IBM, Inc., Armonk, NY).

RESULTS

Baseline characteristics of the study population are detailed in Table I. Patients in Group 1 were significantly older, had more coronary artery disease and heart failure and more likely to be on anticoagulation than those in Group 2.

| TABLE I | BASELINE CHARACTERISTICS STRATIFIED BY TYPE OF ABLATION CATHETER |
|---------------------|---------------------|---------------------|---------------------|
|                      | COOL FLEX          | THERMOCOOL        | p value |
|                      | Group 1 (n = 12)   | Group 2 (n = 42)   |         |
| Age [years (sd)]    | 53.3 (16.2)        | 39.4 (19.1)        | 0.026   |
| Body mass index [kg/m² (sd)] | 29.3 (6.7)        | 26.5 (4.9)        | 0.13     |
| Male gender         | 6 (50%)            | 12 (28.6%)        | 0.17   |
| Hypertension        | 5 (41.7%)          | 13 (31.0%)        | 0.49   |
| Diabetes mellitus   | 3 (25.0%)          | 2 (4.8%)          | 0.033   |
| Smoking history     | 7 (58.3%)          | 9 (21.4%)         | 0.014   |
| Coronary artery disease | 4 (33.3%)       | 5 (11.9%)         | 0.079  |
| Coronary artery bypass graft | 3 (25%)        | 1 (2.4%)          | 0.008  |
| Congestive heart failure | 8 (66.6%)       | 12 (28.5%)        | 0.016  |
| Anticoagulation     | 6 (50%)            | 6 (14.3%)         | 0.009  |
| Heparin usage       | 2 (16.6%)          | 29 (69%)          | 0.001   |
| Antiplatelet        | 4 (33.3%)          | 10 (23.8%)        | 0.51   |
There were 12 ablations with the Therapy™ Cool Flex™ catheter and 42 ablations with ThermoCool Celsius® catheter. There was a greater incidence of steam pop in the Therapy™ Cool Flex™ group (33.3% vs. 2.4%, \( p < 0.05 \)) (Figure 1) along with higher incidence of pericardial effusion (16.6% vs. 0%, \( p < 0.05 \)) (Figure 2).

One of the two patients that had a pericardial effusion went into tamponade and subsequently passed away on the table. This patient had severe ischemic cardiomyopathy with an ejection fraction at 10% and was undergoing a ventricular tachycardia (VT) ablation for VT storm.

There was no difference between the types of ablations done with the catheters (Table II). However, there were more right and left atrial ablations performed with the Thermocool catheter as compared with the Cool Flex catheter.

### Table II

<table>
<thead>
<tr>
<th>Type of Arrhythmia</th>
<th>Cool Flex (Group 1)</th>
<th>ThermoCool (Group 2)</th>
<th>( P ) value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Atrial flutter</td>
<td>1 (8.3%)</td>
<td>3 (7.1%)</td>
<td>0.89</td>
</tr>
<tr>
<td>Atrial fibrillation</td>
<td>5 (41.6%)</td>
<td>11 (26.1%)</td>
<td>0.30</td>
</tr>
<tr>
<td>Atrial tachycardia</td>
<td>0 (0%)</td>
<td>4 (9.5%)</td>
<td>0.27</td>
</tr>
<tr>
<td>Supraventricular tachycardia</td>
<td>1 (8.3%)</td>
<td>5 (11.9%)</td>
<td>0.73</td>
</tr>
<tr>
<td>Ventricular tachycardia</td>
<td>3 (25%)</td>
<td>6 (14.2%)</td>
<td>0.38</td>
</tr>
<tr>
<td>Premature ventricular complex</td>
<td>2 (16.6%)</td>
<td>15 (35.7%)</td>
<td>0.21</td>
</tr>
<tr>
<td>Wolf Parkinson White</td>
<td>1 (8.3%)</td>
<td>12 (28.5%)</td>
<td>0.15</td>
</tr>
</tbody>
</table>

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catheter (Table III). In addition, more ablation procedures in Group 2 required heparin compared to the Group 1 procedures signaling that the Group 2 cases were mostly more complex arrhythmias cases.

The composite endpoint of failed procedure, steam pop, effusion, tamponade or death was significantly higher in the Cool Flex group (50% vs. 2.4%, \(p < 0.0001\)). After multivariate adjustment for baseline demographics, anti-coagulation and location of ablation site, Cool Flex catheter use was significantly associated with worse outcomes (odds ratio 33.3 [3.30-336], \(p = 0.003\)).

**DISCUSSION**

In this study, we observed a significantly higher incidence of steam pop and pericardial effusion in the Cool Flex group, contrary to the study by Ramoul et al. [5] that was not able to show a statistical difference between the two catheters.

**TABLE IV**

<table>
<thead>
<tr>
<th></th>
<th>Cool Flex (Group 1) (n = 12)</th>
<th>ThermoCool (Group 2) (n = 42)</th>
<th>(p) value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Failed procedure</td>
<td>1.0% (8.3%)</td>
<td>0.0% (0.0%)</td>
<td>0.059</td>
</tr>
<tr>
<td>Steam pop</td>
<td>4.0% (33.3%)</td>
<td>1.0% (2.4%)</td>
<td>0.001</td>
</tr>
<tr>
<td>Pericardial effusion</td>
<td>2.0% (16.7%)</td>
<td>0.0% (0.0%)</td>
<td>0.007</td>
</tr>
<tr>
<td>Tamponade</td>
<td>1.0% (8.3%)</td>
<td>0.0% (0.0%)</td>
<td>0.059</td>
</tr>
<tr>
<td>Death</td>
<td>1.0% (8.3%)</td>
<td>0.0% (0.0%)</td>
<td>0.059</td>
</tr>
</tbody>
</table>

Knowing that the Cool Flex catheter was used as per the recommendation of the company with maximum power of 30 watts and max temperature set at 40 degrees compared to the ThermoCool group whereby a power of 40 watts was delivered for some cases with max temperature of 42 degrees. The Ramoul et al. study [5] was done on right atrial flutters only but our study included several types of ablation procedures. The risk of causing a pericardial effusion during the ablation of the cavitricuspid isthmus is low given the thickness of the isthmus and this could have been the reason why there was no pericardial effusion in the Ramoul et al. study [5].

Experimental studies have demonstrated that at a given electrode size and electrode-tissue contact force, the delivered power and the resulting rise in tissue temperatures are the important parameters that determine the radiofrequency lesion size [6]. An open-irrigated catheter (by cooling the RF delivering catheter electrode tip) allows delivery of higher RF power to the myocardial tissue (even at atrial sites of low blood flow), enabling deeper, and larger lesions [7].

In addition, this external irrigation also reduces the risk of char and thrombus formation at the interface between electrode tip and tissue and reduces the occurrence of steam pops [8], therefore, open-irrigated catheters are the state-of-the-art technology for radiofrequency ablation. Newer irrigated catheters aim to improve the irrigation efficacy. The Cool Flex catheter provide a theoretical better irrigation flow by providing more outflows around the whole tip [8,9].

A study conducted by J. Moreno et al. compared the newer catheters ThermoCool SF, Cool Flex and Blazer™ Open-Irrigated, with the standard ThermoCool catheter [10]. This study showed that the newer catheters showed lower temperature readings compared with the ThermoCool. No major efficacy or safety differences were found at tangential applications; however, at perpendicular applications: the Cool Flex created smaller lesions than SF and readily induced steam pops at 50 W without temperature control.
The success of radiofrequency ablation is entirely dependent on full transmural lesion formation [11]. If too much energy is applied, there can be serious complications like perforation of the atrium, tamponade or embolisms [12]. Of all the factors that influence lesion formation, local catheter endocardial contact geometry (penetration depth and incident angle) is the least well controlled due to a lack of soft tissue contrast in the fluoroscopy images used to track catheter location.

There is a large amount of data illustrating the important effect that catheter/endocardial contact has on electrical coupling [13], naturally occurring cooling, heat accumulation, maximum temperature, the transient response of each, and the resulting lesion formation [11, 13]. In addition, preliminary studies have shown that there are significant differences in initial measured electrical impedance depending on catheter/tissue angle even at the same penetration depth [14]. Despite this, and the fact that unknown endocardial contact geometry is a well known limitation of the procedure [15], how lesion formation is affected by the incidence angle of the catheter requires further elucidation.

Catheter angle had a very large effect on lesion volume with up to a two-fold difference in size between the angle extremes. As the angle between the catheter and the tissue became more acute for a given depth, more electrode surface was in contact with myocardium. Thus, this easily explains a larger lesion volume without increasing lesion depth. However, lesion depth also increased greatly for very acute angles, due to a larger heating surface having less curvature directly under the electrode. It is clear that catheter contact geometry (not just penetration depth) is important not only when it comes to the ultimate lesion dimensions but also to the T_max induced in the tissue. At greater penetration depths, catheter angle played an even more significant role in lesion formation parameters with the more acute angles (particularly 15°) having the greatest depths, widths and volumes [16].

Conventional irrigation catheters have theoretical limitations with respect to the efficiency of irrigation.

Indeed, on a planar tissue surface, irrigation holes positioned at the interface between the catheter and the tissue surface are obstructed by the tissue itself and most of the irrigation will be delivered through the unobstructed holes into the blood pool. A more ‘intelligent’ design of irrigation, i.e. mainly distributed to the tissue-electrode interface during RF application with parallel positioning of the catheter, has theoretical benefits, as does internal global irrigation. One of the problems with conventional irrigation is unequal cooling of the catheter tip and the tissue, such that lesion size and growth are dependent upon catheter-tip orientation relative to the tissue [16].

The multiple variables that effect power delivery and lesion growth (contact force, current density, edge effects, active, and passive cooling of the tissue) mean that in clinical practice the electrophysiologist only has the vaguest of notions as to how a lesion is being formed, although catheters for direct lesion assessment are being developed [17]. It is this variability that can result in complications from RF catheter ablation including steam pops, which can result in perforation and cardiac tamponade and may also lead to inadequate lesion formation resulting in either procedural failure or recurrence of arrhythmia due to temporary, sublethal myocardial damage.

Furthermore, the Cool Flex catheter has a specific design with a fully irrigated and flexible tip. However, the theoretical benefits of this catheter-tip design of uniform cooling and hence more predictable lesion formation did not result in demonstrable clinical safety in the present study. One of the reasons why this catheter-design did not translate into clinical safety could be the ridged shaft with flat wiring system compared to the spiral wiring system of the ThermoCool catheter. This is of a considerable importance in a beating heart as the catheter body has to react to the heart beat during RF application. In addition, the distal part of the catheter, particularly between the electrodes, does not bend the fact that negates the benefit of the flexible tip. In details, the Cool Flex catheter has a straight end that starts 1 cm before the proximal electrodes whereas the ThermoCool catheter bends all the way till the distal electrode which decreases the axial force to the tissue (Figure 3).
Study limitations
This is a retrospective study from a single tertiary center and of small sample size with likely referral and selection bias. However, having a larger study population might have diluted the differences between the catheters. In addition, we could not enroll more patients in Group 1 because the use of this catheter has decreased significantly after observing the complications associated with it. Finally, as this study was performed in the clinical setting utilizing the Cool Flex catheter and the conventional ThermoCool catheter, no estimation of intramural tissue temperature, thrombus formation or contact force on the electrode-tissue interface was possible.

CONCLUSION
The current study showed that in patients undergoing irrigated RF ablation the Therapy™ Cool Flex™ RF ablation catheter significantly increases the risk of steam pop formation and increases the risk of pericardial effusion. A large and randomized trial is needed to confirm our findings.

REFERENCES
15. Calkins H, Brugada J, Packer DL et al. HRS/EHRA/ECAS expert consensus statement on catheter and surgical ablation of atrial fibrillation: recommendations for personnel, policy, procedures and follow-up. A report of the Heart Rhythm Society (HRS) Task Force on Catheter and Surgical Ablation of Atrial Fibrillation developed in partnership with the European Heart Rhythm Association (EHRA) and the European Cardiac Arrhythmia Society (ECAS); in collaboration with the American College of cardiology (ACC), American Heart Association (AHA), and the Society of Thoracic Surgeons (STS). Endorsed and approved by the governing bodies of Catheter Angle Affects Cardiac Lesion Formation, the American College of Cardiology, the American Heart Association, the European Cardiac Arrhythmia Society, the European Heart Rhythm Association, the Society of Thoracic Surgeons, and the Heart Rhythm Society. Europace 2007; 9: 335-79.