Single Center Experience with a Closed-Loop Irrigated Ablation Catheter for the Treatment of Human Paroxysmal and Persistent Atrial Fibrillation

RAHUL N. DOSHI, MD, FHRS, LESLEY OLEY, MS, ANJALI DOSHI, STEVEN CEBALLOS, CVT and FAUSTO MENDEZ, CVT

St. Jude Medical Center, Fullerton, CA
Fullerton Cardiovascular Medical Group, Fullerton, CA
University of California Irvine, CA

ABSTRACT. Open-irrigated electrode catheters are commonly used for ablation for atrial fibrillation (AF). There are scant data available for closed-loop irrigation for ablation for AF. Proponents of open-irrigated catheters state greater patient safety from char formation, less impedance rises, and greater lesion depth. There are fundamental biophysical differences in the biophysics of the energy delivered with closed-loop catheters, and the efficacy for paroxysmal AF and persistent/longstanding is not well established. A total of 336 patients (62 ± 11 years, 66% male) underwent ablation for AF with a 4-mm closed-loop catheter (Chili tip, Boston Scientific, San Jose, CA) between March 2006 and June 2009. All ablation lesions were delivered in a temperature-control mode with maximum temperature 40–42°C and maximum power 40 W. Pulmonary venous antral isolation was most commonly performed for patients with paroxysmal AF versus a wide area circumferential approach with roof line and left atrial isthmus line for chronic atrial fibrillation. All procedures were performed using three-dimensional mapping (NavX, St. Jude Medical, Minneapolis, MN). Antiarrhythmic medications were continued up to 1–3 m post ablation, and up to two cardioversions were allowed during this period. Follow-up including ambulatory electrocardiogram recordings occurred every 3 months. Success was defined as arrhythmia-free and off antiarrhythmic medications at 1 year after most recent ablation. Acute procedural success defined as complete pulmonary vein isolation was achieved in all 336 patients. There were three patients with tamponade treated successfully, one case of pulmonary vein stenosis, and one vascular bleed requiring intervention. Thirty-two patients were lost to follow-up. A second ablation was required for 11.6% of paroxysmal AF and 42.8% of persistent AF cases. After one procedure, 1-year success rates for patients were 81.1% for paroxysmal AF and 57.2% for persistent/longstanding AF. After two procedures, 92.8% of patients with paroxysmal AF and 78.4% of patients with persistent/longstanding AF were free of arrhythmia at 1 year. Closed-loop irrigated ablation catheters are safe and efficacious for the ablation of atrial fibrillation. More investigation is warranted to determine if there are any benefits over open-irrigation ablation.

KEYWORDS. atrial fibrillation, catheter ablation.
achieving acute pulmonary vein isolation, which remains
the only required endpoint with current recommenda-
tions. The use of linear lesions, ablation of complex
fractionated electrograms (CFAE), and autonomic gang-
lia ablation vary from center to center. However, the vast
majority of published experience utilizes open-irrigation
radiofrequency energy ablation. This includes a large
pivotal trial that has resulted in one catheter being
approved specifically for AF ablation. Proponents of
open-irrigation cite favorable properties including lesion
depth, decreased impedance rises, and decreased char
formation.

While the clinical efficacy of open-irrigated catheters is
well established, there have been studies demonstrating
variable lesion depth, shape, and location based on the
irrigant or saline “cloud.” This feature of open irrigation
is highly dependent on local factors such as direction and
magnitude of blood flow, and catheter location including
electrode depth within the tissue. Closed-loop irrigated
radiofrequency ablation provides ablative tip cooling
by internally circulating coolant, and has been demon-
strated to provide similar advantages in obtaining lesion
depth while providing consistent lesion size that is not
dependent on these factors. Utilization of closed-loop
irrigation also allows for tissue interface temperature-
controlled ablation, which is predictive of lesion depth.
However, the experience with closed-loop irrigation in
the treatment of atrial fibrillation is less established and
limited to pulmonary vein isolation alone. Thus, the vast
majority of these procedures are performed with open-
irrigation. Estimates in the United States currently
demonstrate about 85% AF procedures utilizing open-
irrigation catheters (personal communication, Boston
Scientific, San Jose, CA; and Biosense Webster, Diamond
Bar, CA).

We present our acute and 1-year follow-up single-
center experience utilizing closed-loop irrigation in the
management of symptomatic, drug-refractory paroxys-
mal AF (PAF) and persistent or chronic AF (CAF).

**Methods**

**Patient characteristics**

We report a retrospective analysis of 336 patients un-
dergoing catheter ablation for symptomatic drug-refrac-
tory AF between March 2006 and June 2009. Of these
patients, 66% were male, with a mean age of 62 ± 11
years at time of first ablation. Baseline patient demo-
graphics are shown in Table 1. Patients had failed 1.8
(PAF) or 1.7 (CAF) drugs, with a much higher percentage
of patients with CAF having failed amiodarone (16%
and 58% for PAF and CAF, respectively). Patients with
CAF had larger left atrial size than PAF (49 ± 8 versus
43 ± 4 mm, respectively, p<0.05). Both groups had
similar incidence of hypertension, diabetes, and coronary
disease. Patients with CAF were more likely to have
significant valvular disease or congestive failure. Thirty-
two patients were lost to follow-up within 1 year of
ablation. The remaining 304 patients were divided into
paroxysmal AF (N=142) and persistent/longstanding
AF (N=162). All patients gave informed consent for the
procedure.

**Electrophysiologic study/ablation**

Vascular access was obtained from right and left femoral
veins and occasionally the right internal jugular vein.
Transseptal access was performed in each case under
both fluoroscopic and intracardiac echocardiography
visualization (Boston Scientific) for both mapping and
ablation catheter access. Three-dimensional mapping/
reconstruction of the left atrium/pulmonary veins was
performed with the NavX system (St. Jude Medical,
Minneapolis, MN) and a 20-pole circular mapping
catheter. A representative lesion set for patients with
persistent or longstanding AF is shown in Figure 1.
Transesophageal echocardiographic imaging was per-
formed in all patients in persistent AF, and activated
clotting times (ACT) during procedure were maintained
between 300 and 350 s. Heparin was reversed with
intravenous protamine prior to vascular sheath removal,
and anticoagulation was restarted 6 h after sheath
removal.

**Ablation parameters**

Catheter ablation was performed with the 4-mm tip
closed tip ablation catheter (Chili II Catheter, Boston
Scientific) and the Maestro 3000 generator (Boston Sci-
entific), in a temperature control mode with a maximum
temperature setting of 42°C and maximum power setting
of 40 W. Lesion duration was limited to 30 s with a target
of 50% electrogram height reduction.

**Follow-up**

Patients were discharged home on postoperative day 1
and follow-up was arranged at 1 week, and 1, 3, 6, 9, and

Table 1: Patient demographics for patients with paroxysmal and persistent/longstanding atrial fibrillation

<table>
<thead>
<tr>
<th></th>
<th>Paroxysmal (N=142)</th>
<th>Persistent (N=162)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years)</td>
<td>61 ± 11</td>
<td>63 ± 11</td>
</tr>
<tr>
<td>Males (%)</td>
<td>116 (82%)</td>
<td>136 (84%)</td>
</tr>
<tr>
<td>Left ventricular ejection fraction (%)</td>
<td>57 ± 5</td>
<td>51 ± 7</td>
</tr>
<tr>
<td>Left atrium dimension (mm)</td>
<td>43 ± 4</td>
<td>49 ± 9*</td>
</tr>
<tr>
<td>Duration atrial fibrillation (months)</td>
<td>23 ± 9</td>
<td>27 ± 11</td>
</tr>
<tr>
<td>Number of drugs</td>
<td>1.8 ± 0.3</td>
<td>1.7 ± 0.4</td>
</tr>
<tr>
<td>Amiodarone use</td>
<td>23 (16%)</td>
<td>94 (58%)*</td>
</tr>
<tr>
<td>Hypertension</td>
<td>78 (55%)</td>
<td>93 (57%)</td>
</tr>
<tr>
<td>Diabetes</td>
<td>4 (2.8%)</td>
<td>8 (4.9%)</td>
</tr>
<tr>
<td>Coronary disease</td>
<td>7 (4.9%)</td>
<td>13 (8.0%)</td>
</tr>
<tr>
<td>Valvular disease</td>
<td>11 (7.7%)</td>
<td>19 (12%)</td>
</tr>
<tr>
<td>Congestive failure</td>
<td>0 (0%)</td>
<td>6 (3.7%)*</td>
</tr>
</tbody>
</table>

*p<0.05.
12 months. Warfarin was maintained 2–3 months post procedure unless recurrent arrhythmia or CHADS2 score $\geq$2 (in which case warfarin continued for a minimum of 6 months). Antiarrhythmic medications were continued 1–3 month post procedure and then discontinued unless recurrent arrhythmia. Patients underwent ambulatory electrocardiogram (ECG) monitoring (7-, 21-, or 30-day event recorder) at 3, 6, 9, and 12 months unless they had an implantable device (pacemaker or defibrillator). Recurrences within the first 3 months were not counted as ablative failures, and if persistent underwent cardioversion (maximum of two performed during first 3 months). Recurrences after 3 months were considered ablation failures.

Statistical analysis

Statistical analysis for comparisons between groups and basic calculations were performed with Microsoft Excel (Microsoft, Seattle, WA). Statistical comparisons were made performing Student’s t-Test (two tails, equal variance). A p-value of less than 0.05 was considered significant. Kaplan–Meier curves where generated using Minitab v15.1.1.0 non-parametric distribution analysis right sensoring (Minitab, State College, PA). The 32 patients lost to follow-up or with incomplete data were excluded from analysis.

Results

The results are summarized in Table 2. Acute pulmonary vein isolation confirmed with demonstration of entrance block was achieved in all patients. A representative lesion set for patients with persistent AF is shown in Figure 1. Our lesion set in this analysis for persistent AF employed is similar to other studies employing open irrigation. Patients with persistent AF had procedures that were longer ($177 \pm 34$ versus $142 \pm 18$ min, $p<0.05$), and were associated with greater exposure to fluoroscopy ($22.3 \pm 7.5$ versus $18.9 \pm 3.4$ min, $p<0.05$). Patients with paroxysmal AF rarely required cardioversion after the procedure (1.4%). Cardioversion was quite common among patients with persistent AF (22.8%, $p<0.05$). Procedural success rates for 1 year off medications are depicted graphically in Figure 2. A much lower percentage of patients with paroxysmal AF than persistent AF required a second procedure (11.6% versus 42.8%, $p<0.05$).

Table 2: Results for patients with both paroxysmal and persistent/longstanding atrial fibrillation

<table>
<thead>
<tr>
<th></th>
<th>Paroxysmal (N=142)</th>
<th>Persistent/longstanding (N=202)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Procedure time (min)</td>
<td>$142 \pm 18$</td>
<td>$177 \pm 34^*$</td>
</tr>
<tr>
<td>Fluoroscopy time (min)</td>
<td>$18.9 \pm 3.4$</td>
<td>$22.3 \pm 7.5^*$</td>
</tr>
<tr>
<td>Patients with cardioversion in 3 months n (%)</td>
<td>2 (1.4)</td>
<td>46 (22.8)$^*$</td>
</tr>
<tr>
<td>Patients requiring re-do</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ablation n (%)</td>
<td>$16 (11.6)$</td>
<td>$83 (42.8)^*$</td>
</tr>
<tr>
<td>Patients with 1-year follow up</td>
<td>138</td>
<td>194</td>
</tr>
<tr>
<td>1-year success</td>
<td></td>
<td></td>
</tr>
<tr>
<td>One procedure n (%)</td>
<td>$112 (81.1)$</td>
<td>$111 (57.2)^*$</td>
</tr>
<tr>
<td>Two procedures n (%)</td>
<td>$128 (92.8)$</td>
<td>$152 (78.4)^*$</td>
</tr>
<tr>
<td>Complications</td>
<td></td>
<td></td>
</tr>
<tr>
<td>CVA/TIA n (%)</td>
<td>0 (0)</td>
<td>0 (0)</td>
</tr>
<tr>
<td>Tamponade n (%)</td>
<td>1 (0.7)</td>
<td>2 (1.0)</td>
</tr>
<tr>
<td>PV stenosis n (%)</td>
<td>1 (0.7)</td>
<td>0 (0)</td>
</tr>
<tr>
<td>Atrial-esophageal fistula n (%)</td>
<td>0 (0)</td>
<td>0 (0)</td>
</tr>
<tr>
<td>Vascular bleed n (%)</td>
<td>0 (0)</td>
<td>1 (0.5)</td>
</tr>
<tr>
<td>Hematoma n (%)</td>
<td>1 (0.7)</td>
<td>0 (0)</td>
</tr>
</tbody>
</table>

*p<0.05.
The first procedure success rates were much different between the two groups, with 81.1% success in patients with paroxysmal AF versus 57.2% in patients with persistent AF (p < 0.05). Efficacy after a second procedure remained significantly different, with 92.8% success off medications at 1 year for patients with PAF versus 78.4% success in patients with CAF (p < 0.05).

The cumulative probability of remaining free of AF post ablation is shown in Figure 3. For the 138 patients with PAF and 1-year follow-up, the arrhythmia-free probability was 0.92 with confidence limits of 0.80 and 0.96. For the 194 patients with CAF, the probability of remaining arrhythmia-free was 0.78 with confidence limits of 0.63 and 0.84.

Discussion

Our data support the use of closed-irrigation ablation for the treatment of both PAF and CAF. Our reported efficacy and safety profile is similar to previous published results for open-irrigated ablation, including those employing a similar lesion set. A prior report has demonstrated that the use of closed-loop irrigation is efficacious for the ablation of AF. Bhargava et al reported that the use of closed-loop irrigation for the use of ostial or segmental pulmonary vein isolation. They reported consistent efficacy for the treatment of PAF. However, the overall ablation lesion volume was likely not as large as we are currently reporting, with an average of 10 lesions applied per vein to achieve isolation. Indeed, the relatively high incidence of pulmonary vein stenosis suggests ablation at the ostium compared to the antrum. Our technique, like others reported with open irrigation, involves delivering many more lesions more proximally in the antrum and body of the left atrium.

Previous reports have demonstrated similar lesion size and depth for both open-irrigated and closed-loop irrigated catheters. However, some reports have also reported a higher likelihood of char formation with higher powers for closed-loop irrigation. The general consensus is that the saline irrigant would decrease the likelihood of any significant char by simply “washing-away” any potential nidus for thrombus formation. However, our concern is that since the irrigant “cloud” is highly variable depending on the relative flow of saline from the catheter, the degree of external cooling is also variable among various positions along the electrode–tissue interface. This finding has been supported by in vitro investigation. Indeed, catheter position for open irrigation ablation including depth of penetration in the tissue and tissue geometry has been shown to create highly variable cooling and thus highly variable lesions.

Closed-loop or internally cooled ablation catheters have an advantage in that they are less subject to variables such as catheter position or local blood flow. Moreover, open irrigation eliminates a highly predictive measurement for lesion depth—the tissue-electrode...
interface. Most open-irrigated ablation is performed in a power-control mode, including what is currently approved for AF ablation.7 Thiagalingam and associates12 have reported that with closed-loop irrigation, the temperature at the electrode–tissue interface is highly predictive of lesion depth, much like conventional radiofrequency ablation. Moreover, temperature-controlled ablation reduces the risk of char formation at the electrode when higher powers are employed.9

Everett et al9 have made extensive comparisons between ablation technologies in vitro. While no catheter was devoid of limitations, there was an equal “complication” rate between closed- and open-irrigated ablation. Open-irrigation was associated with larger volume lesions, although the depths between open- and closed-irrigation were similar.9 Closed-loop irrigation was associated with higher char formation at higher powers, while open irrigation was associated with eccentric lesions and saline blisters.9 We believe that these comparisons are useful but are missing an important practical component of catheter ablation, as there is a tradeoff between deeper lesions and safety. The ability to predict lesion depth is more important in ablation given the concern for collateral damage. Indeed, most proponents of open-irrigation ablation report a maximum duration for ablation less than 30 s, with many operators moving the catheter constantly.13 This timing is empiric, and is despite the fact that open-irrigation ablation requires a longer time for maximum tissue depth than conventional or closed-loop irrigation.9 In comparison, the time to achieve maximum depth with closed-loop irrigation is shorter,9 and much more in keeping with the current clinical practice of more constant catheter movement.

Conclusion
Closed-loop irrigation is safe and efficacious for the ablation of AF, even when employing an extensive lesion set. Given the favorable biophysical characteristics with faster lesion formation and predictable lesion formation despite variability in anatomic factors, closed-loop radiofrequency ablation might have benefits over open irrigation. A prospective, randomized comparison between these two ablation techniques would allow us to gain insight into any possible advantage for either technology.

References
1. Calkins H, Brugada J, Packer D, 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 Society (EHRS) 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 the American College of Cardiology, the American Heart Association, the European Heart Rhythm Association, the Society of Thoracic Surgeons, and the Heart Rhythm Society. Europace 2007; 9:335–379.