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

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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.

Introduction

Catheter ablation for atrial fibrillation (AF) is now widely utilized therapy in patients with symptomatic, drug-refractory arrhythmia. Techniques for ablation involve
achieving acute pulmonary vein isolation, which remains the only required endpoint with current recommendations. The use of linear lesions, ablation of complex fractionated electrograms (CFAE), and autonomic ganglia 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 demonstrated 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 paroxysmal AF (PAF) and persistent or chronic AF (CAF).

Methods

Patient characteristics

We report a retrospective analysis of 336 patients undergoing catheter ablation for symptomatic drug-refractory 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 demographics 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 performed 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 Scientific), 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
12 months. Warfarin was maintained 2–3 months post procedure unless recurrent arrhythmia or CHADS2 score ≥ 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 ± 34 versus 142 ± 18 min, p < 0.05), and were associated with greater exposure to fluoroscopy (22.3 ± 7.5 versus 18.9 ± 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 ± 18</td>
<td>177 ± 34*</td>
</tr>
<tr>
<td>Fluoroscopy time (min)</td>
<td>18.9 ± 3.4</td>
<td>22.3 ± 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>
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*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.5,4 A prior report has demonstrated that the use of closed-loop irrigation is efficacious for the ablation of AF.11 Bhargava et al11 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.11 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.9,10 However, some reports have also reported a higher likelihood of char formation with higher powers for closed-loop irrigation.9 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 along various positions along the electrode–tissue interface. This finding has been supported by in vitro investigation.9 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.9

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

Figure 2: Single procedure and two procedure success rates at 1 year for paroxysmal and persistent atrial fibrillation.

Figure 3: Kaplan–Meier estimates of arrhythmia-free post ablation for 1 year after most recent ablation. The table insert shows absolute numbers, arrhythmia-free probabilities and confidence limits.
interface. Most open-irrigated ablation is performed in a power-control mode, including what is currently approved for AF ablation. Thiagalingam and associates 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.

Everett et al 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. Closed-loop irrigation was associated with higher char formation at higher powers, while open irrigation was associated with eccentric lesions and saline blisters. 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. 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. In comparison, the time to achieve maximum depth with closed-loop irrigation is shorter, 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

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