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Acute Safety of an Open-Irrigated Ablation Catheter with 56-Hole Porous Tip for Radiofrequency Ablation of Paroxysmal Atrial Fibrillation: Analysis from 2 Observational Registry Studies

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Acute Safety from 2 AF Ablation Registries. Introduction: This report presents safety data on the use of a new open-irrigation radiofrequency ablation (RFA) catheter with a 56-hole porous tip in 742 patients enrolled in 2 US prospective, multicenter observational registry studies representing real-world use of the catheter.

Methods: This analysis is comprised of patients who underwent RFA of drug-refractory recurrent symptomatic paroxysmal atrial fibrillation (AF). Acute adverse events (AEs) were collected and categorized by seriousness, timing, and relatedness, with 7 days of follow-up data in one study and at least 120 days of data from a 1-year follow-up in the other. Acute serious adverse events (SAEs) that were identified as potentially related to the device and/or procedure were adjudicated by an independent safety committee.

Results: A total of 30 patients (4.0%) in the combined studies experienced an acute SAE related to the device and/or procedure, which was similar in the subset of patients age 65 and over (4.2%). These SAEs included 1.2% cardiac tamponade/perforation, 0.7% pericarditis, 0.5% pulmonary events, and 0.8% vascular access complications. No myocardial infarction, stroke, transient ischemic attack, or atrioesophageal fistulas within 7 days postprocedure were reported. In the study with extended follow-up, 1 pulmonary vein stenosis and 1 esophageal injury were seen beyond 7 days postprocedure (0.2% each). There were no device or procedure related deaths.

Conclusion: Results from 2 large observational studies demonstrated that a new porous tip RFA catheter was safe for the treatment of drug refractory, recurrent, symptomatic paroxysmal AF, including treatment of older patients (≥65 years). (J Cardiovasc Electrophysiol, Vol. 25, pp. 852-858, August 2014)

Introduction

Radiofrequency (RF) catheter ablation has proven efficacy for treating many types of supraventricular arrhythmias and has become an increasingly important clinical tool for treating atrial fibrillation (AF). Electrical isolation of the pulmonary veins (PVs) from the left atrium is the cornerstone for most AF ablation procedures and is considered the best interventional method to treat AF in the paroxysmal AF population.

Efforts to improve the efficacy and safety of RF ablation (RFA) led to the development of the open irrigation 6-hole catheter, which was the first catheter approved for ablation of AF in 2009. The catheter design has now been improved with 56 irrigation holes to enhance cooling and reduce irrigation flow rate. The new porous tip provides uniform cooling over the entire tip rather than only localized cooling at the distal end, allowing more efficient heat dissipation and RF delivery. Park et al. reported on better procedural efficiency to reach complete pulmonary vein isolation (PVI), as compared to the 6-hole catheter, with a significant reduction in irrigation volume administered (approximately 500 mL less).

Until now, safety data for the new catheter have largely been limited to unmonitored, single-center experiences. The primary objective of this paper is to report real world acute safety data from 2 prospective US observational registry studies using the porous tip catheter for the treatment of drug refractory, recurrent, symptomatic paroxysmal AF. It is believed that these registry results represent a wider range

1 acute safety, atrial fibrillation, catheter ablation, complications, thermocool SF catheter

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T. Hunter is an employee of S2 Statistical Solutions, which has contracted with Biosense Webster to provide programming, statistical design, analysis, and interpretation of catheter ablation studies. B. Herweg serves as consultant/advisory board member to Biosense Webster and St. Jude Medical. H. Wang received honoraria relevant to this topic from Biosense Webster. R. Fishele is on the medical advisory board of Biosense Webster. Other authors: No disclosures.

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of techniques, operator experience, and patient profiles than past studies, and as such will be generalizable to a broader range of clinical practice.

A secondary objective of this paper is to report on any differences in acute safety between patients age 65 and older and younger patients, as AF prevalence increases with age and adults age 65 years and older comprise an estimated 82% of all AF patients in the United States.9

Methods

Study Design

This analysis includes data from 2 prospective, multicenter observational registry studies (SFAF and IUAF) performed in the United States and involving subjects who underwent RFA of drug-refractory recurrent symptomatic paroxysmal AF. The characteristics of the studies are outlined in Table 1. The SFAF Study is currently ongoing and all available safety information at the time of the database lock is included in this analysis, which includes a minimum of 120 days follow-up on all patients. The IUAF Study included only 7-day follow-up and is closed to enrollment, with all follow-up completed and all of the available safety information at the time of database lock included in this report. Both studies were approved by institutional review boards at all clinical sites, and all patients provided informed consent before collection of any study related data.

Study data from both of these registries was independently monitored. Acute events that were predefined as potentially related to the device and/or procedure (“primary” events) were adjudicated by an independent safety committee.

Patient Eligibility Criteria

Eligible study subjects were patients 18 years or older with drug-refractory, recurrent, symptomatic paroxysmal AF. Both studies excluded patients with AF secondary to electrolyte imbalance or thyroid disease, reversible, or of non-cardiac cause; previous ablation for AF; AF episodes that lasted 30 days or longer; uncontrolled heart failure, or NYHA class III or IV heart failure; documented atrial thrombus or other abnormality on preablation imaging; contraindication to anticoagulation; stroke, cardiac surgery, unstable angina, myocardial infarction (MI) or percutaneous coronary intervention within the past 3 months; awaiting cardiac transplantation; heart disease for which corrective surgery was anticipated within 6 months; enrollment in other investigational drug or device study; or who were pregnant.

AF Ablation Procedure

PVI was performed in both studies using 3-dimensional electroanatomical mapping (Carto® 3 System; Biosense Webster, Inc.) and a 56-hole porous tip ablation catheter (Navistar® ThermoCool® SF Catheter; Biosense Webster, Inc.) according to standard of care at each institution. The IUAF study also required utilization of the SoundStar® Catheter for 3-D intracardiac echocardiography (ICE). RF ablation was performed with a power range of 15–50W. A minimum irrigation flow rate of 8 mL/minute was recommended for power levels ≤30W and 15 mL/minute for power levels >30W. Procedural details were recorded, including ablation targets, fluid delivered, maximum power, validation method used to verify complete PVI, and procedure time. Following ablation, anticoagulation therapy and the use of other medications were at the discretion of the study physician.

Safety Analysis

The safety evaluations in this analysis included the collection of all adverse events (AEs) occurring over the course of the study, whether or not they were related to the device or procedure. Exacerbations of preexisting conditions, if observed at follow-up and considered by the study physician to be clinically significant, were also included. The reporting period for AEs began with access (opening of the femoral vein). Any adverse changes to the subject’s health that occurred before access, but after the screening period, were considered to be a part of the patient’s medical history. All AEs that were ongoing at the time of the 7-day follow-up contact were followed until the events were considered resolved or stable. Arrhythmia events were not considered to be related to the device or procedure. Electrocardiogram findings were also collected at baseline and

### Table 1: Characteristics of Studies

<table>
<thead>
<tr>
<th>Study Identifier</th>
<th>SFAF Study</th>
<th>IUAF Study</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of subjects</td>
<td>508 patients</td>
<td>234 patients</td>
</tr>
<tr>
<td>Clinical sites</td>
<td>45 US centers</td>
<td>26 US centers</td>
</tr>
<tr>
<td>Type of study</td>
<td>Observational</td>
<td>Observational</td>
</tr>
<tr>
<td>Study objective</td>
<td>To measure the real-world procedural outcomes associated with the Navistar® ThermoCool® SF catheter with the Carto® 3 system</td>
<td>To measure the real-world acute procedural outcomes associated with the Navistar® ThermoCool® SF catheter with the Carto® 3 System and real time intracardiac ultrasound using the SoundStar® catheter with CartoSOUND® software</td>
</tr>
<tr>
<td>Outcome Evaluations</td>
<td>During RFA, immediately post-RFA, discharge, day 7, month 6, and 1 year</td>
<td>During RFA, immediately post-RFA, discharge, and day 7</td>
</tr>
</tbody>
</table>

AF = atrial fibrillation; RFA = radiofrequency ablation.
discharge and were reviewed for safety as a part of both studies. The primary focus of this report is on serious adverse events (SAEs) related to the device and/or procedure. This includes any events occurring within 7 days postprocedure in the IUAF study or to at least 120 days in the SFAF study.

Predefined primary events were adjudicated by an independent safety committee. These primary events included any of the following SAEs occurring within 7 days postprocedure, except as otherwise specified: any event resulting in death, atrioesophageal fistula (discovered at any time postprocedure), atrial perforation, cardiac tamponade, MI, stroke or cerebrovascular accident (CVA), thromboembolism, transient ischemic attack (TIA), diaphragmatic paralysis, pneumothorax, heart block, PV stenosis (≥70% reduction in diameter, discovered at any time postprocedure), respiratory insufficiency, and pericardial effusion.

**Statistical Analysis**

The number and percentages of events were summarized for categorical variables (e.g., complications). Means, standard deviations, medians, minimums and maximums were calculated for continuous variables (e.g., ejection fraction). Pearson’s chi-squared tests were used to compare the counts of events across age cohorts.

**Results**

**Patient Characteristics**

The safety data analysis included 742 enrolled patients (SFAF = 508, IUAF = 234). The baseline patient characteristics for both studies are presented in Table 2. The majority of the patients were Caucasian non-Hispanic males. Approximately half of all patients were over 65 years old (SFAF = 48.4%, IUAF = 48.7%), and mean age was 62.1 years. The mean time since diagnosis of AF was 1,594 days in SFAF and 1,619 in IUAF. A majority of the patients were on anticoagulant therapy at the time of the index ablation procedure, all of which occurred within 7 days postprocedure, including 23 patients in the IUAF study or out to at least 120 days in the SFAF study. This includes any events occurring within 7 days postprocedure, except as otherwise specified: any event resulting in death, atrioesophageal fistula (discovered at any time postprocedure), atrial perforation, cardiac tamponade, MI, stroke or cerebrovascular accident (CVA), thromboembolism, transient ischemic attack (TIA), diaphragmatic paralysis, pneumothorax, heart block, PV stenosis (≥70% reduction in diameter, discovered at any time postprocedure), respiratory insufficiency, and pericardial effusion.

**Serious Adverse Events**

Of the combined 742 patients in the 2 studies, 85 (11.5%) experienced a total of 102 SAEs during the procedure or within the 7 days postprocedure, including 23 patients in the IUAF study (9.8%) who experienced 24 events and 62 patients (12.2%) in the SFAF study who experienced 78 events. Only 30 (4.0%) of the 742 patients experienced an acute SAE that was related to the device or the procedure. By study, there were 21 patients (4.1%) in the SFAF study and 9 patients (3.8%) in the IUAF study with acute device or procedure related SAEs.

Older patients (age 65 and over) experienced more SAEs than younger patients (age <65 years), though the difference was not statistically significant (13.6% vs. 9.4%, P-value 0.0735). There was no significant difference in the number of device and/or procedure related SAEs for older and younger patients (4.2% vs. 3.9%, P-value 0.8683).

In the combined patient population, 9 patients (1.2%) experienced cardiac tamponade or perforation events as a result of the index ablation procedure, all of which occurred within 7 days of the procedure. Of these 9 events, 6 (1.7%) occurred in patients ≥65 years of age. Evaluation of the 9 cases occurring at the index procedure showed that standard ablation parameters were used during all of these cases with no deviation in procedural characteristics from the general cohort. Maximum power utilized during these ablations ranged from 30 to 50 watts.

Additionally, 4 patients (0.5%) had pulmonary events that included bronchospasm, pulmonary edema, and respiratory insufficiency, and 5 patients (0.7%) experienced pericarditis meeting the definition of an SAE. None of the pulmonary events and just 1 of pericarditis events (0.3%) occurred in patients ≥65 years of age. Six patients (0.8%), of whom 4 (1.1%) were ≥65, had serious vascular access...
Complications, including bleeding and hematoma of the groin, along with femoral artery aneurysm and pseudoaneurysm. No atrioesophageal fistula, MI, stroke or CVA, TIA, thromboembolism, diaphragmatic paralysis, pneumothorax, or heart block events were reported within 7 days postprocedure in either trial.

In addition to the acute SAEs, 3 patients of 508 in the SFAF study experienced SAEs more than 7 days after their index ablation procedure that were related to the device or procedure, as of the database lock date. These later events included 1 case of stenosis of the left inferior PV, 1 esophageal injury, and 1 cardiac tamponade subsequent to a repeat ablation procedure. All 3 patients who experienced late SAEs were <65 years of age.

The case of esophageal injury was reviewed and adjudicated by the independent safety committee as not being consistent with AE fistula. Although an endoscopy at 23 days postprocedure showed a small pinpoint defect, a CT scan showed no evidence of abnormal communication between the atrium and esophagus. The esophagus was prophylactically stented and 10 days later the defect had completely healed. During the patient’s ablation procedure, an esophageal temperature probe was utilized and power delivery was limited to 30–35W in the vicinity of the esophagus and anterior wall.

The patient with PV stenosis was a 30-year-old male with multiple comorbid conditions. Coronary computed tomography angiography showed approximately 80% stenosis of the left inferior PV and 40–50% stenosis of the left superior PV. Both veins were successfully stented at 7 months postablation.

Summary counts of all SAEs within 7 days of the index ablation, along with details of those events that were related to the device and/or procedure, are presented in Table 3.

Deaths

There were no deaths reported in the IUAF study and 4 deaths reported in the SFAF study. None of these deaths were adjudicated by the safety committee as being related to the device or the procedure. The causes of death included liver cancer, cardiogenic shock because of pancreatitis, respiratory insufficiency resulting from severe chronic interstitial lung disease, and respiratory failure subsequent to pneumonia and small cell carcinoma. All 4 patients were >65 years old (range: 71–77 years) with significant comorbidities and all deaths occurred greater than 7 days postprocedure.

Discussion

The results from these 2 large multicenter observational studies demonstrate the safety of the new catheter design in a real world setting with a large, heterogeneous patient population involving multiple clinician operators with various levels of experience. Overall rates of device or procedure related SAEs were similar to rates published in other large studies of catheter ablation for AF. In addition, there was no difference between older patients (age 65 and over) and younger (age < 65) patients with respect to overall rates of these events.

There were no device or procedure related deaths in these registries, as reviewed and adjudicated by the independent safety monitoring committee. In 2009, a retrospective case series reported on the prevalence and cases of fatal outcome in catheter ablation of AF. This large series reported that death is an uncommon complication associated with catheter ablation of AF, with the incidence of death being 1 of every 1,000 patients. The absence of device and/or procedure related death in these studies further supports the past results.

The safety data presented in this report are consistent with the published safety data on open irrigation catheter ablation for AF. In a 2009 worldwide survey of 182 centers performing catheter ablation for AF, major procedure-related complications occurred in 4.5% of patients. Also, an analysis of 6 studies utilizing the 6-hole irrigation design reported a combined 4.9% (63/1275) procedural complication rate within 7 days postprocedure. The current studies, with a combined 30 patients of 742 (4.0%) who experienced procedure and/or device related events within 7 days, demonstrated a comparable level of acute safety for the new porous tip catheter.

There are a number of recent publications reporting on use of the catheter. An abstract by Santucci et al. reported on initial experience with the new catheter in a cohort of 20 AF patients at a single site, and observed major complications including 3 cardiac tamponade/perforations and 2 atrioesophageal fistulas. Park et al. reported on a prospective multicenter study that compared the new porous tip catheter to the 6-hole ThermoCool® Catheter (Biosense Webster, Inc.) using different ablation modes. The investigators observed no differences in AE rates between the 2 catheter technologies even when using different ablation modes. Reported events included 1 patient of 78 in the ThermoCool® SF Catheter (Biosense Webster, Inc.) group with a TIA 2 days after PVI and 1 patient of 82 in the ThermoCool® Catheter group with a cardiac tamponade requiring thoracotomy. In the other studies reporting on use of the porous tip catheter, 1 tamponade and no deaths were reported in a total of 207 patients ablated with the ThermoCool® SF Catheter (Biosense Webster, Inc.).

In the current studies, involving multiple sites and operators with various levels of experience, the combined rate of cardiac tamponade/perforation events recorded after index ablations (1.2%) is consistent with 2 large worldwide surveys that reported a 1.2% tamponade rate in 2005 and a 1.3% rate in 2009. Although no patient in the current studies developed an atrioesophageal fistula, there was 1 patient with an esophageal injury. Incidence of esophageal ulcer or thermal lesion has been reported to be as high as 11–14% in patients who have undergone an AF ablation. Although the rate of thermal esophageal injury is unknown in the current studies because routine endoscopy was not performed, it is clear that esophageal injury is not an uncommon finding and does not lead to a fistula in the vast majority of cases. Therefore, it is difficult to draw any conclusions from this isolated case.

In these 2 studies, there was just 1 related SAE for a congestive heart failure (CHF) event in 742 patients (0.1%). A 2012 safety analysis including 1,275 patients from 6 FDA clinical studies utilizing the 6-hole NAVISTAR® ThermoCool® Catheter (Biosense Webster, Inc.) reported heart failure or CHF exacerbation events in 13 of 1,275 patients (1.0%). The average fluid volume delivered through the catheter in the current studies was 957.8 mL, as
compared with 1,591.0 mL in the pivotal study for the 6-hole catheter design.\(^\text{19}\) It is likely that the reduction in the type of SAEs that typically result from fluid overload, such as CHF exacerbation, is related to the reduction in fluid delivery.

One of the limitations of these studies is that they are observational studies with no comparison arm. Although a control arm is not typical of post-FDA approval studies, the studies are closely monitored for any safety signals that would warrant additional evaluation. Another limitation of the IUAF study is that it is limited to a 7-day follow-up and thus does not allow for full knowledge of late-occurring complications.

### Conclusions

This safety analysis demonstrated that catheter ablation utilizing a new open irrigation RFA catheter with 56-hole porous tip is safe for the treatment of drug-refractory recurrent symptomatic paroxysmal AF, with no unanticipated device or procedure related AEs. In addition to demonstrating overall safety in a heterogeneous population representative of what is seen in normal clinical practice, safety was consistent in the subpopulation of patients age 65 and older.

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The authors would like to acknowledge the contribution of the SFAF and IUAF study investigators and Global Safety Investigators listed below.

**SFAF Study (45 US centers)**

1. Central Baptist Hospital (Lexington, KY)—Dr. Gery Tomassoni
2. Florida Hospital (Orlando, FL)—Dr. Scott Pollak
3. Scottsdale Healthcare Research Institute, Scottsdale Healthcare/Shea Medical Center (Scottsdale, AZ)—Dr. Andy Tran
4. St. Vincent’s Ambulatory Care, Inc. (Jacksonville, FL)—Dr. Saumil Oza
5. Alaska Heart Institute, LLC. (Anchorage, AK)—Dr. Steven Compton
6. St. Joseph’s Hospital of Atlanta/Emory University (Atlanta, GA)—Dr. Anshul Patel
7. JFK Medical Center (Atlantic, FL)—Dr. Robert Fishe
8. Cardiovascular Research Foundation of Louisiana (Baton Rouge, LA)—Dr. Kenneth Civello
9. Bethesda North Hospital (Cincinnati, OH)—Dr. Gaurang Gandhi
10. University of Cincinnati (Cincinnati, OH)—Dr. Alexander Costea
11. Riverside Methodist Hospital (Columbus, OH)—Dr. Sreedhar Billakanty
12. Florida Hospital Memorial Medical Center (Daytona Beach, FL)—Dr. James Wang

*Three patients in the SFAF study (2 ≥65 years and 1 <65 years) had no reported adverse events, but ablation data were incomplete at the time of analysis.

*In addition, 1 patient in the SFAF study experienced a tamponade event after a repeat ablation procedure, 119 days post study index procedure.

SFAF = registry identifier; IUAF = registry identifier; SAE = serious adverse events; TIA = transient ischemic attack.

### TABLE 3

<table>
<thead>
<tr>
<th>Study</th>
<th>SFAF</th>
<th>IUAF</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Total</td>
<td>&lt;65 years</td>
</tr>
<tr>
<td>Safety cohort (n)(^*)</td>
<td>508</td>
<td>262</td>
</tr>
<tr>
<td><strong>Summary counts</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total count of acute SAEs</td>
<td>78</td>
<td>36</td>
</tr>
<tr>
<td>Procedure or device-related acute SAEs</td>
<td>23</td>
<td>13</td>
</tr>
<tr>
<td>Patients with an acute SAE</td>
<td>62 (12.2%)</td>
<td>28 (10.7%)</td>
</tr>
<tr>
<td>Patients with procedure or device-related acute SAE</td>
<td>21 (4.1%)</td>
<td>12 (4.6%)</td>
</tr>
<tr>
<td>Deaths</td>
<td>0 (0.0%)</td>
<td>0 (0.0%)</td>
</tr>
</tbody>
</table>

**Individual-related events**

- Arrhythmias/ventricular fibrillation
- Abdominal pain
- Anemia
- Cardiac tamponade/perforation\(^*\)
- Congestive heart failure
- Diaphragmatic paralysis
- Dysphagia
- Heart block
- Hematuria
- Hyponatremia
- Hypotension
- Myocardial infarction
- Noncardiac chest pain
- Pericarditis
- Pulmonary events (total)
- Bronchospasm
- Pneumothorax
- Pulmonary edema
- Respiratory insufficiency
- Stroke/TIA/cardiovascular accident
- Thromboembolism
- Vascular access events (total)
- Femoral artery aneurysm
- Postprocedural hematoma
- Puncture site hemorrhage
- Vascular access complication
- Vascular pseudoaneurysm

**Summary counts**

- Thromboembolism 2 (0.9%) 1 (0.8%) 1 (0.9%)
- Pulmonary events (total) 3 (0.6%) 3 (1.1%) 0 (0.0%)
- Pericarditis 3 (0.6%) 3 (1.1%) 0 (0.0%)
- Pulmonary events (total) 3 (0.6%) 3 (1.1%) 0 (0.0%)
- Bronchospasm 0 (0.0%) 0 (0.0%) 0 (0.0%)
- Pneumothorax 0 (0.0%) 0 (0.0%) 0 (0.0%)
- Pulmonary edema 1 (0.2%) 1 (0.4%) 0 (0.0%)
- Respiratory insufficiency 2 (0.4%) 2 (0.8%) 0 (0.0%)
- Stroke/TIA/cardiovascular accident 0 (0.0%) 0 (0.0%) 0 (0.0%)
- Vascular access events (total) 2 (0.4%) 1 (0.4%) 1 (0.4%)
- Femoral artery aneurysm 1 (0.2%) 1 (0.4%) 0 (0.0%)
- Postprocedural hematoma 0 (0.0%) 0 (0.0%) 0 (0.0%)
- Puncture site hemorrhage 0 (0.0%) 0 (0.0%) 0 (0.0%)
- Vascular access complication 1 (0.2%) 0 (0.0%) 1 (0.4%)
- Vascular pseudoaneurysm 0 (0.0%) 0 (0.0%) 0 (0.0%)
- Deaths 0 (0.0%) 0 (0.0%) 0 (0.0%)

\(^*\)In addition, 1 patient in the SFAF study experienced a tamponade event after a repeat ablation procedure, 119 days post study index procedure.
References


