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QUARTERLY FOCUS ISSUE: HEART RHYTHM DISORDERS

The Risk of Thromboembolism and Need for Oral Anticoagulation After Successful Atrial Fibrillation Ablation

Sakis Themistoclakis, MD,* Andrea Corrado, MD,* Francis E. Marchlinski, MD,† Pierre Jais, MD,‡ Erica Zado, PAC,† Antonio Rossillo, MD,* Luigi Di Biase, MD,§ Robert A. Schweikert, MD,‖ Walid I. Saliba, MD,¶ Rodney Horton, MD,§ Prasant Mohanty, MBBS, MPH,§ Dimpi Patel, DO,§ David J. Burkhardt, MD,§ Oussama M. Wazni, MD,¶ Aldo Bonso, MD,* David J. Callans, MD,† Michel Haissaguerre, MD,‡ Antonio Raviele, MD,* Andrea Natale, MD§

Mestre-Venice, Italy; Philadelphia, Pennsylvania; Bordeaux-Pessac, France; Austin, Texas; and Akron and Cleveland, Ohio

Objectives The aim of this multicenter study was to evaluate the safety of discontinuing oral anticoagulation therapy (OAT) after apparently successful pulmonary vein isolation.

Background Atrial fibrillation (AF) is associated with an increased risk of thromboembolic events (TE) and often requires OAT. Pulmonary vein isolation is considered an effective treatment for AF.

Methods We studied 3,355 patients, of whom 2,692 (79% male, mean age 57 ± 11 years) discontinued OAT 3 to 6 months after ablation (Off-OAT group) and 663 (70% male, mean age 59 ± 11 years) remained on OAT after this period (On-OAT group). $CHADS_2$ (congestive heart failure, hypertension, age [75 years and older], diabetes mellitus, and a history of stroke or transient ischemic attack) risk scores of 1 and ≥2 were recorded in 723 (27%) and 347 (13%) Off-OAT group patients and in 261 (39%) and 247 (37%) On-OAT group patients, respectively.

Results During follow-up (mean 28 ± 13 months vs. 24 ± 15 months), 2 (0.07%) Off-OAT group patients and 3 (0.45%) On-OAT group patients had an ischemic stroke ($p = 0.06$). No other thromboembolic events occurred. No Off-OAT group patient with a $CHADS_2$ risk score of ≥2 had an ischemic stroke. A major hemorrhage was observed in 1 (0.04%) Off-OAT group patient and 13 (2%) On-OAT group patients ($p < 0.0001$).

Conclusions In this nonrandomized study, the risk–benefit ratio favored the suspension of OAT after successful AF ablation even in patients at moderate-high risk of TE. This conclusion needs to be confirmed by future large randomized trials. (J Am Coll Cardiol 2010;55:735–43) © 2010 by the American College of Cardiology Foundation

Atrial fibrillation (AF) is a major risk factor for thromboembolism, and oral anticoagulation therapy (OAT) is usually recommended for patients at higher risk of this complication (1,2). Catheter ablation has emerged as a promising cure for AF (3,4). Reported success rates range from 45% to 95% (3). One of the potential advantages of AF ablation is the possibility of discontinuing OAT after a successful procedure. However, the safety of this strategy has not yet been demonstrated in large randomized studies.

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Two recent expert consensus documents recommended continuing OAT indefinitely, at least in patients at high

From the *Dell'Angelo Hospital, Mestre-Venice, Italy, †University of Pennsylvania, Philadelphia, Pennsylvania, ‡Hopital Cardiologique du Haut-Leveque, Bordeaux-Pessac, France, §Texas Cardiac Arrhythmia Institute at St. David's Medical Center, Austin, Texas; ‖Akron General Hospital, Akron, Ohio; and the ¶Cleveland Clinic Foundation, Cleveland, Ohio. Dr. Jaïs has received presentation fees from BW/Bard. Dr. Schweikert has received speaker honoraria from GlaxoSmithKline, Sanofi-Aventis, St. Jude Medical, and Boston Scientific. Dr. Saliba has received speaker honoraria from J&J, Medtronic, St. Jude Medical, and Boston Scientific. Dr. Horton is on the Speakers' Bureau of Medtronic, St. Jude Medical, and Boston Scientific; is a consultant for Hansen Medical and Atritech; and is on the clinical advisory panel of Biosense-Webster. Dr. Burkhardt is a chief medical advisor for Stereotaxis. Dr. Haissaguerre has received presentation fees from BW/Bard. Dr. Raviele is on the Speakers' Bureau of Biosense-Webster, and is a consultant to and advisory board member of Sanofi-Aventis. Dr. Natale has received a research grant from St. Jude Medical and speaker honoraria from St. Jude Medical, Medtronic, Biosense-Webster, and Boston Scientific.

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Abbreviations and Acronyms

AF = atrial fibrillation
CI = confidence interval
ECG = electrocardiogram
HR = hazard ratio
INR = international normalized ratio of prothrombin time
LA = left atrial/atrium
OAT = oral anticoagulation therapy
TE = thromboembolic events
TIA = transient ischemic attack
TTM = transtelephonic monitoring

risk of thromboembolic events (TE) (3,4). Despite these recent recommendations, the use of OAT after an apparently successful ablation procedure is still controversial, and some centers implement a policy of withdrawing OAT even in the majority of patients at high risk of TE (17% of 42 centers worldwide surveyed in a recent questionnaire) (5). To clarify this issue, we conducted the present study by collecting data from 5 high-volume centers that have, over the years, implemented a consistent strategy with regard to the suspension of OAT after successful ablation.

Methods

Patient population. Consecutive patients referred to the 5 participating centers between January 2001 and December 2005 who had discontinued OAT after successful AF ablation were enrolled in the study (Off-OAT group) and were compared with patients who had undergone AF ablation in the period January 2003 to December 2005 and continued OAT (On-OAT group). Patients with prosthetic valves were excluded from the study. On referral, all patient data were prospectively recorded in a computerized database. Both Off- and On-OAT groups were divided into 3 subgroups according to their TE risk profile. Patients' risk profiles were evaluated by means of the $CHADS_2$ (congestive heart failure, hypertension, age [75 years or older], diabetes mellitus, history of stroke or transient ischemic attack) score. This index is based on a points system in which 2 points are assigned for a history of TIA or stroke and 1 point for each of the other risk factors. A $CHADS_2$ score of 0 is considered to indicate a low risk of TE, a score of 1 indicates a moderate risk, and a score of 2 or more indicates a high risk (6).

All patients selected for pulmonary vein isolation had a history of symptomatic drug-resistant paroxysmal, persistent, or permanent AF (1). A follow-up of at least 1 year after the last ablation and 6 months after OAT discontinuation was required for inclusion in the study. Before the ablation procedure, all patients gave their written informed consent as approved by the institutional ethics committee, and patient data were collected in accordance with institutional ethics guidelines.

Ablation strategy. The ablation strategy included pulmonary vein isolation at the ostial or antral level, guided by a circular mapping catheter. Intracardiac echocardiography or angiography was used to locate the pulmonary veins and define the ostium or the antrum of the veins. Additional linear lesions, ablation of complex fractionated electrograms, and isolation of the superior vena cava were performed per institutional preference. The details of the ablation procedures have been presented elsewhere (7–9).

Anticoagulation protocol. All patients were monitored overnight in the hospital, and were usually discharged from 1 to 3 days after the procedure depending on institutional policy. The OAT with adjusted-dose warfarin was restarted in all patients on the evening of the ablation procedure and continued for at least 3 to 6 months to maintain the international normalized ratio of prothrombin time (INR) between 2 and 3 (10). After this period, each center decided the long-term anticoagulation strategy according to local institutional policy and the individual characteristics of each patient. As a general rule, OAT was discontinued, regardless of the $CHADS_2$ score, if patients did not experience: 1) any recurrence of atrial tachyarrhythmias (AF or atrial flutter/tachycardia longer than 1 min); 2) severe pulmonary vein stenosis (pulmonary vein narrowing >70%); and 3) severe left atrial (LA) mechanical dysfunction (absence of A-wave on pulsed Doppler transmitral recording). Patients with early recurrence of AF or episodes of atrial flutter and a $CHADS_2$ score of 1 or more were maintained on OAT for at least 6 months; subsequently, OAT was discontinued in patients without arrhythmic recurrence in the last 3 months off antiarrhythmic drugs. After OAT discontinuation, patients were treated with aspirin, 81 to 325 mg/day. Patients with a $CHADS_2$ score of 1 or more who developed a recurrence of atrial tachyarrhythmia after discontinuation were restarted on OAT. For the purpose of the present study, the data collected up to the time when these patients restarted OAT were included in the analysis.

Post-ablation management and follow-up. Follow-up examinations were routinely scheduled at 1 to 3, 6, and 12 months after the procedure and every 6 months thereafter. Seventy-nine percent of patients were seen up to the 1-year follow-up by the physician in the center where the ablation was performed. For all patients who were unable to be seen in the first year and thereafter, their status was assessed by a nurse practitioner via telephone and monitoring tests were obtained by the referring physician. In any case, all data collected in this way were also evaluated by the physician of the center where the ablation procedure had been performed. An electrocardiogram (ECG) was obtained routinely in all patients within 1 month after the procedure and at each follow-up examination. Each study institution had different strategies for identifying AF recurrences prior to OAT discontinuation. These included Holter recordings (at 1, 3, and 6 months) in 86% of patients and/or transtelephonic monitoring (TTM) (ranging from continuous for 5 months in 76% of patients to 1-month blocks immediately after, at 6 to 12 weeks, and at 6 months after AF ablation in 14%) in 90% of patients. Patients who underwent TTM were asked to transmit their rhythm data every time they had symptoms compatible with arrhythmias, and 1 to 3 times per day even if they were asymptomatic. Interrogation