Journal of the American College of Cardiology
© 2013 by the American College of Cardiology Foundation
Published by Elsevier Inc.

Vol. 61, No. 16, 2013
ISSN 0735-1097/$36.00
http://dx.doi.org/10.1016/j.jacc.2012.09.033

Long-Term Outcomes After Cryoballoon Pulmonary Vein Isolation

Results From a Prospective Study in 605 Patients

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Objectives The purpose of this study was to investigate long-term outcomes of freedom from atrial fibrillation (AF) after pulmonary vein (PV) isolation using cryoballoon ablation with balloon-size selection based on individual PV diameters.

Background Data are lacking on long-term outcomes from cryoablation and on the most effective balloon size.

Methods This was a prospective observational study involving 605 consecutively enrolled patients with symptomatic paroxysmal AF (n = 579) or persistent AF. Cryoballoon size was based on magnetic resonance imaging and/or conventional angiograms. Patients were followed up every 3 months during the first year after discharge and every 6 months in the second year. After 24 months, follow-up was on an outpatient basis with documented AF episodes recorded.

Results The PV isolation was achieved without touch-up in 91.1% of patients, using the smaller balloon in 26.7%, the larger balloon in 25.6%, and both balloons in 47.7% of patients. Follow-up data for >12 months (median 30 months; interquartile range 18 to 48 months) were available for 451 patients, 278 (61.6%) of whom were free of AF recurrence with no need for repeat procedures after the 3-month blanking period. Rates of freedom from AF after 1, 2, and 3 repeat procedures (using cryoballoon or radiofrequency ablation with similar success rates) were 74.9%, 76.2%, and 76.9%, respectively. Use of the smaller balloons or both balloons produced the highest rates of long-term freedom from AF. Phrenic nerve palsy occurred in 12 patients (2%), resolving within 3 to 9 months.

Conclusions Rates of long-term freedom from AF after cryoballoon ablation are similar to those reported for radiofrequency ablation. A choice between balloons may improve outcomes. (J Am Coll Cardiol 2013;61:1707–12) © 2013 by the American College of Cardiology Foundation

Ablation procedures for circumferential pulmonary vein isolation (PVI) by encircling the pulmonary vein (PV) antrum have become the therapy of choice for drug-refractory symptomatic focal atrial fibrillation (AF) (1), with a continual increase in the number of procedures performed annually (2). The majority of these procedures are carried out with radiofrequency energy, but the use of cryoballoon ablation is growing rapidly.

Most published cryoballoon studies have focused on 12-month outcomes (4–6), and current consensus guidelines note the need for follow-up data beyond 12 months from large patient populations (7,8). We conducted a prospective, large-scale, long-term investigation into the outcomes of cryoablation in consecutively enrolled patients with AF. The choice between the 23-mm and 28-mm balloons was made for individual veins on the basis of the anatomies of the PV ostia. We also included the option of using 2 balloon sizes in the same patient.

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Methods

This was a prospective observational study involving 605 patients enrolled consecutively at our institute. All patients provided informed consent, and the study was approved by the local institutional ethics committee.

Enrolled patients had symptomatic paroxysmal AF, defined as per Heart Rhythm Society (HRS)/European Heart Rhythm Association (EHRA) consensus guidelines (8), with a history of failed treatment with antiarrhythmic drugs class Ic and/or III.

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Manuscript received May 30, 2012; revised manuscript received September 11, 2012, accepted September 11, 2012.

Abbreviations and Acronyms

AF = atrial fibrillation
ECG = electrocardiography
LA = left atrium
LS = left superior
PNP = phrenic nerve palsy
PV = pulmonary vein
PVI = pulmonary vein isolation

Exclusion criteria were as published previously (4). Transesophageal echocardiography was performed on all candidates to exclude the presence of thrombi.

Ablation procedures and choice of balloon size followed what has been described previously (4). Any phenprocoumon anticoagulation therapy was continued, with a target international normalized ratio of 2.0 to <3.0. A double transseptal puncture was performed to access the left atrium (LA) in the first 253 patients. In the succeeding patients, the LA was accessed by a single transseptal puncture from the right femoral vein, and a steerable 12-F inner diameter sheath (FlexCath, Medtronic, Minneapolis, Minnesota) was employed. Balloon occlusion was assessed with the help of 50% diluted contrast medium injected into the PV and confirmed within the first minute of cryoenergy application (Fig. 1).

In the 518 patients treated between 2005 and 2010, a 20-polar Lasso catheter (Biosense Webster, Diamond Bar,

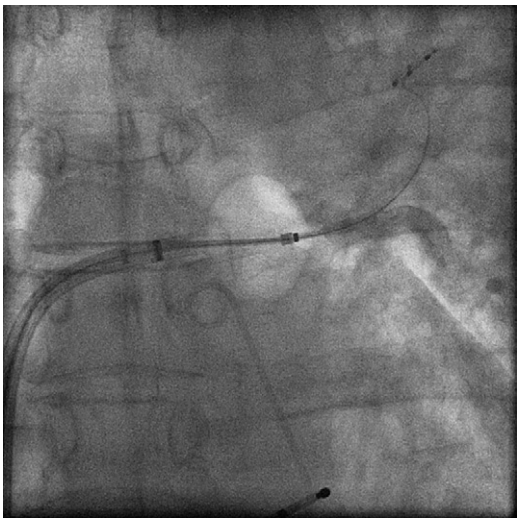

Figure 1 Example of Successful Balloon Occlusion Guided by the Achieve Catheter

Fluoroscopy image of the inflated 28-mm balloon at the antrum of the left superior pulmonary vein with the Achieve.

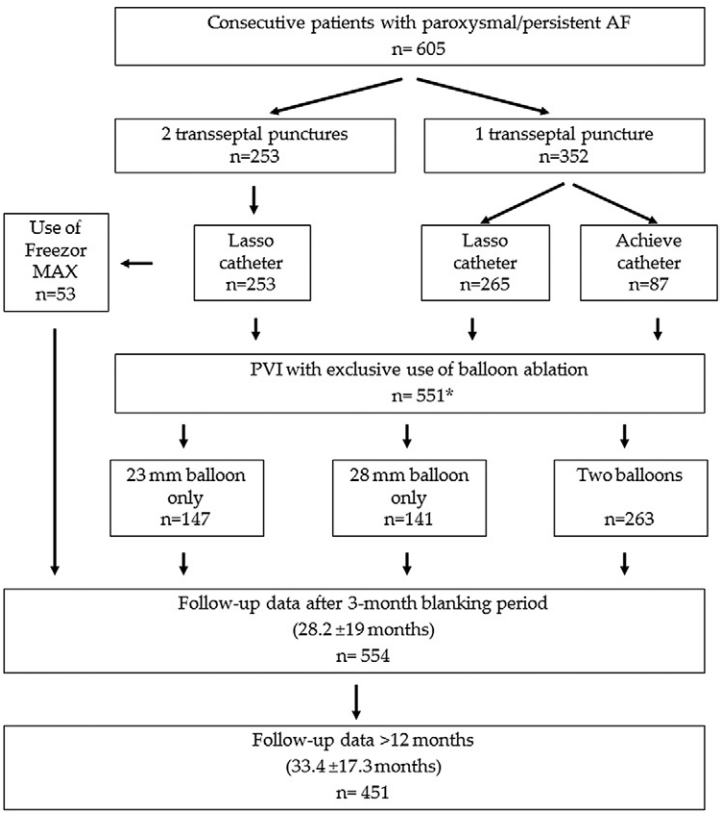

Figure 2 Patient Flow

Schematic representation of the flow of atrial fibrillation (AF) patients through the study. All 53 patients who needed touch-up procedures were treated in the early study phase using the Lasso catheter. *Procedural data missing for 1 patient. PVI = pulmonary vein isolation.