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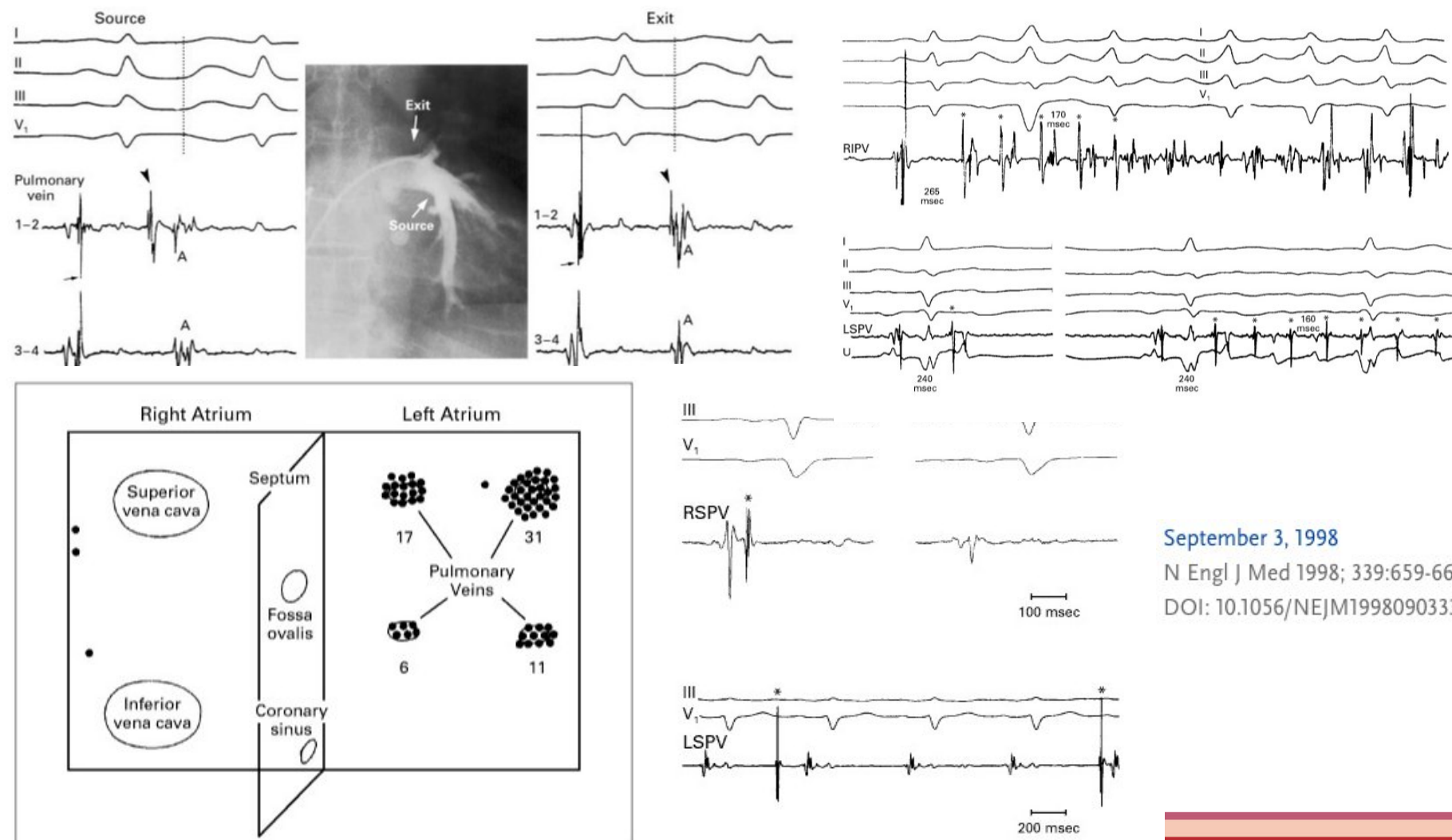
ARITMOLOGIA CLINICA E INTERVENTISTICA.

**LA CRIOABLAZIONE PER TRATTARE TUTTE LE
FORME DI FIBRILLAZIONE ATRIALE**

Roberto Verlato
Camposampiero-Cittadella

Spontaneous Initiation of Atrial Fibrillation by Ectopic Beats Originating in the Pulmonary Veins

Michel Haïssaguerre, M.D., Pierre Jaïs, M.D., Dipen C. Shah, M.D., Atsushi Takahashi, M.D., Méléze Hocini, M.D., Gilles Quiniou, M.D., Stéphane Garrigue, M.D., Alain Le Mouroux, M.D., Philippe Le Métayer, M.D., and Jacques Clémenty, M.D.



September 3, 1998

N Engl J Med 1998; 339:659-666

DOI: 10.1056/NEJM199809033391003

Efficacy and Safety of Circumferential Pulmonary Vein Isolation Using a Novel Cryothermal Balloon Ablation System

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Rochester, Minnesota; and Ribeirão Preto, Brazil

- OBJECTIVES** We sought to evaluate the efficacy and safety of a novel cryothermal balloon ablation system in creating pulmonary vein (PV) isolation.
- BACKGROUND** Pulmonary vein isolation using standard radiofrequency ablation techniques is limited by procedure-related complications, such as thrombus formation and PV stenosis. Cryothermal ablation may reduce the risk of such complications.
- METHODS** Eight dogs underwent circumferential ablation of both superior PVs for either 4 or 8 min using a cryothermal balloon catheter (CryoCath Technologies Inc., Kirkland, Canada). Both fluoroscopy and intracardiac ultrasound (ICE)-guided balloon and Lasso catheter positioning at the PV ostia assessed short-term PV integrity. In six additional dogs, long-term PV integrity was assessed by computed tomography at 16 weeks after ablation.
- RESULTS** Successful electrical isolation was achieved acutely in 14 of 16 (87.5%) PVs and was confirmed in one-week survival studies in 10 of 12 (83%) PVs. Successful isolation was higher in the absence of any peri-balloon flow leak as seen by ICE ($p = 0.015$), and with balloon temperatures $\leq -80^\circ\text{C}$ ($p = 0.015$). Cryolesions were located at the veno-atrial junction and were homogeneous, with intact endothelium and free of thrombus formation. Although limited angiographic PV narrowing was noted in the early follow-up period, no significant PV narrowing was seen long-term. Right phrenic nerve injury was seen in 50% of the animals studied at one week.
- CONCLUSIONS** This novel cryothermal balloon ablation system is effective for isolating PVs, but injury to the right phrenic nerve was noted in this early experience. Further studies are needed to assess the long-term efficacy and safety of this technique. (J Am Coll Cardiol 2005;46:1902-12) © 2005 by the American College of Cardiology Foundation

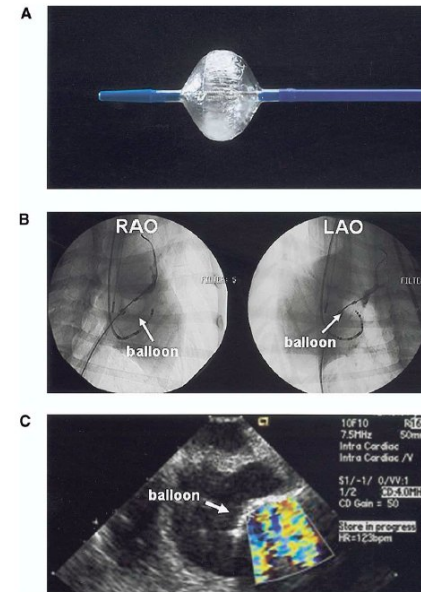


Figure 1. (A) Photograph of the cryothermal balloon catheter. (B) Fluoroscopic image of the inflated balloon engaged at the left superior pulmonary vein (LSPV) orifice (arrows). (C) Intracardiac echocardiographic image of the inflated balloon positioned at the orifice of the LSPV (arrow), illustrating an example of an unsuccessful occlusion of the pulmonary vein orifice, with a peri-balloon flow leak as seen by color Doppler flow. LAO = left anterior oblique projection; RAO = right anterior oblique projection.

1906 Sarabanda et al.
Cryoballoon Ablation of PV

JACC Vol. 46, No. 10, 2005
November 15, 2005:1902-12

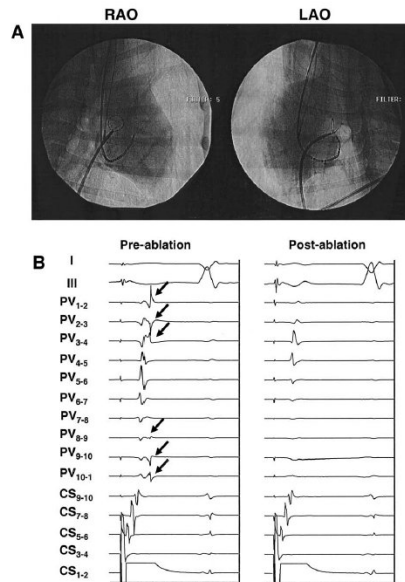
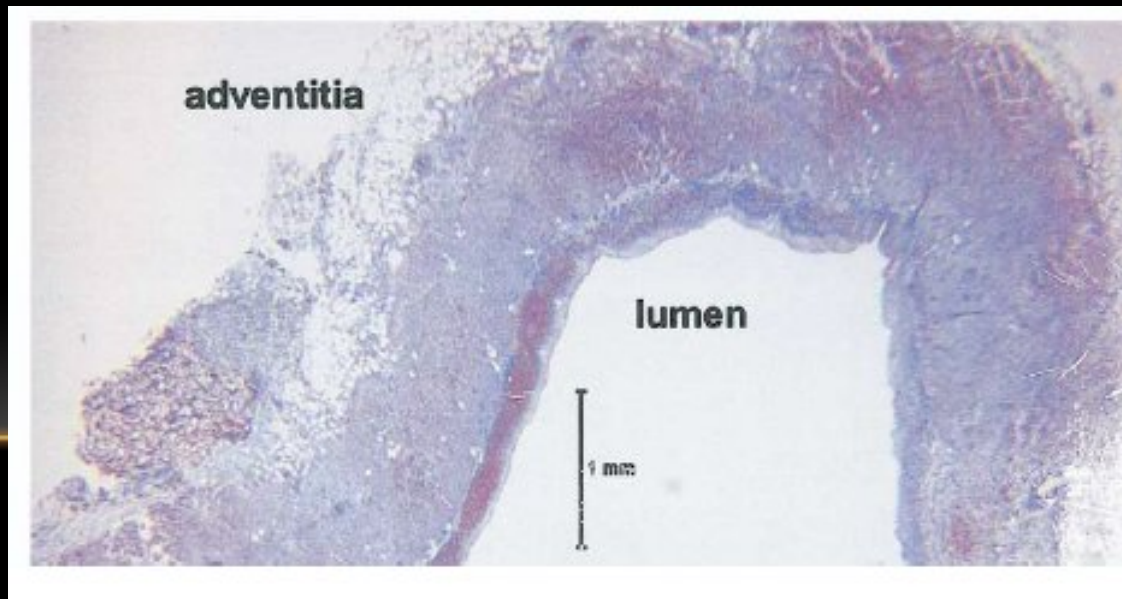


Figure 2. Successful circumferential cryoablation of the left superior pulmonary vein. (A) Fluoroscopic image of the Lasso catheter positioned at the pulmonary vein (PV) ostium. (B) Timeline of the surface electroanatomical and ICE-guided PV catheter ablation.



Pulmonary vein isolation using an occluding cryoballoon for circumferential ablation: feasibility, complications, and short-term outcome

Yves Van Belle*, Petter Janse, Maximo J. Rivero-Ayerza, Andrew S. Thornton, Emile R. Jessurun, Dominic Theuns, and Luc Jordaens

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Received 12 March 2007; revised 1 May 2007; accepted 10 May 2007; online publish-ahead-of-print 14 June 2007

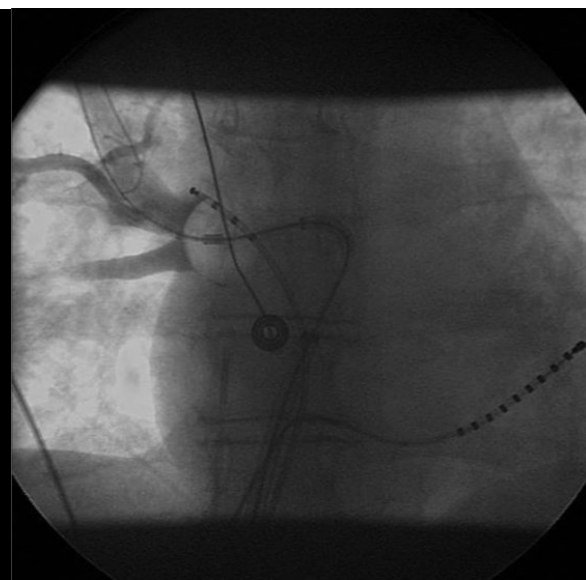


Table 4 Rhythm recording at baseline and during 3 months follow-up

	Baseline	1 month	2 months	3 months	Total FU
Number of recordings	981	1174	1182	1005	3361
Mean heart rate \pm SD	65 \pm 9	68 \pm 8*	68 \pm 9*	66 \pm 8**	
AF recordings (n)	246	108	77	45	230
Mean AF burden \pm SD	0.24 \pm 0.31	0.10 \pm 0.22*	0.08 \pm 0.21***	0.05 \pm 0.15***	0.08 \pm 0.20
Median AF burden (range)	0.14 (0–1)	0 (0–0.88)	0 (0–1)	0 (0–0.80)	0 (0–1)
Patients with AF (n)	57	18	16	13	23

AF, atrial fibrillation; SD, standard deviation.

* $P < 0.01$ vs. baseline.

** $P < 0.05$ vs. baseline.

*** $P < 0.001$ vs. baseline.

2007-2011

23 PUBLICATIONS

FOUR EUROPEAN STUDIES, NON-RANDOMIZED AND THE STOP-AF TRIAL (CRYO VS DRUGS)

Neumann T, Bad Nauheim, Germany, 346 pts, 3 Centers

Circumferential pulmonary vein isolation with the cryoballoon technique: results from a prospective 3-center study. JACC 2008; 52: 273-278

Van Belle Y, Rotterdam, The Nederland, 138 pts

One-year follow-up after cryoballoon isolation of pulmonary veins in patients with paroxysmal atrial fibrillation. EUROPACE 2008; 10: 1271-1276

Malmberg H, Uppsala, Sweden 40 pts

Acute and clinical effects of cryoballoon pulmonary vein isolation in patients with symptomatic paroxysmal and persistent atrial fibrillation. EUROPACE 2008; 10: 1277-1280

Dorwarth U, Munich, Germany, 146 pts: < 83 seconds time to PVI = stable PVI
Pulmonary vein electrophysiology during cryoablation as a predictor for procedural success.

History Card Electrophysiol 2011; 22: 205-211

Cryoballoon Ablation of Pulmonary Veins for Paroxysmal Atrial Fibrillation

First Results of the North American Arctic Front STOP-AF Pivotal Trial

**Douglas L. Packer, James M. Irwin,
Jean Champagne, Peter G. Guerra, Marc Dubuc, Kevin R.
Wheelan, Robert C. Kowal, Vivek Reddy, John W. Lehmann,
Richard G. Holcomb, Jeremy N. Ruskin for the STOP-AF
Cryoablation Investigators**

ACC Atlanta
March 15, 2010

Cryoballoon Ablation of Pulmonary Veins for Paroxysmal Atrial Fibrillation

First Results of the North American Arctic Front (STOP AF) Pivotal Trial

Douglas L. Packer, MD,* Robert C. Kowal, MD,† Kevin R. Wheelan, MD,† James M. Irwin, MD,‡
Jean Champagne, MD,§ Peter G. Guerra, MD,|| Marc Dubuc, MD,|| Vivek Reddy, MD,¶
Linda Nelson, RN,# Richard G. Holcomb, PhD,** John W. Lehmann, MD, MPH,††
Jeremy N. Ruskin, MD,‡‡ for the STOP AF Cryoablation Investigators

*Rochester, Minnesota; Dallas, Texas; Tampa, Florida; Quebec, Canada; New York, New York;
Minneapolis, Minnesota; and Wayland and Boston, Massachusetts*

Objectives

This study sought to assess the safety and effectiveness of a novel cryoballoon ablation technology designed to achieve single-delivery pulmonary vein (PV) isolation.

Background

Standard radiofrequency ablation is effective in eliminating atrial fibrillation (AF) but requires multiple lesion delivery at the risk of significant complications.

Methods

Patients with documented symptomatic paroxysmal AF and previously failed therapy with ≥ 1 membrane active antiarrhythmic drug underwent 2:1 randomization to either cryoballoon ablation (n = 163) or drug therapy (n = 82). A 90-day blanking period allowed for optimization of antiarrhythmic drug therapy and reablation if necessary. Effectiveness of the cryoablation procedure versus drug therapy was determined at 12 months.

Results

Patients had highly symptomatic AF (78% paroxysmal, 22% early persistent) and experienced failure of at least one antiarrhythmic drug. Cryoablation produced acute isolation of three or more PVs in 98.2% and all four PVs in 97.6% of patients. PVs isolation was achieved with the balloon catheter alone in 83%. At 12 months, treatment success was 69.9% (114 of 163) of cryoablation patients compared with 7.3% of antiarrhythmic drug patients (absolute difference, 62.6% [p < 0.001]). Sixty-five (79%) drug-treated patients crossed over to cryoablation during 12 months of study follow-up due to recurrent, symptomatic AF, constituting drug treatment failure. There were 7 of the resulting 228 cryoablated patients (3.1%) with a >75% reduction in PV area during 12 months of follow-up. Twenty-nine of 259 procedures (11.2%) were associated with phrenic nerve palsy as determined by radiographic screening; 25 of these had resolved by 12 months. Cryoablation patients had significantly improved symptoms at 12 months.

Conclusions

The STOP AF trial demonstrated that cryoballoon ablation is a safe and effective alternative to antiarrhythmic medication for the treatment of patients with symptomatic paroxysmal AF, for whom at least one antiarrhythmic drug has failed, with risks within accepted standards for ablation therapy. (A Clinical Study of the Arctic Front Cryoablation Balloon for the Treatment of Paroxysmal Atrial Fibrillation [Stop AF]: NCT00523978) (J Am Coll Cardiol 2013;61:1713-23) © 2013 by the American College of Cardiology Foundation

FIRST
PROSPECTIV
E
RANDOMIZED
TRIAL

Cryo vs drugs,

2:1

randomization

Cryo : 163 pts

Drugs: 82 pts

PAF

STOP AF RESULTS: 95% FREE FROM ANY T.A.

JACC Vol. 61, No. 16, 2013
April 23, 2013:1713-23

Packer *et al.* 1719
The STOP AF Pivotal Trial

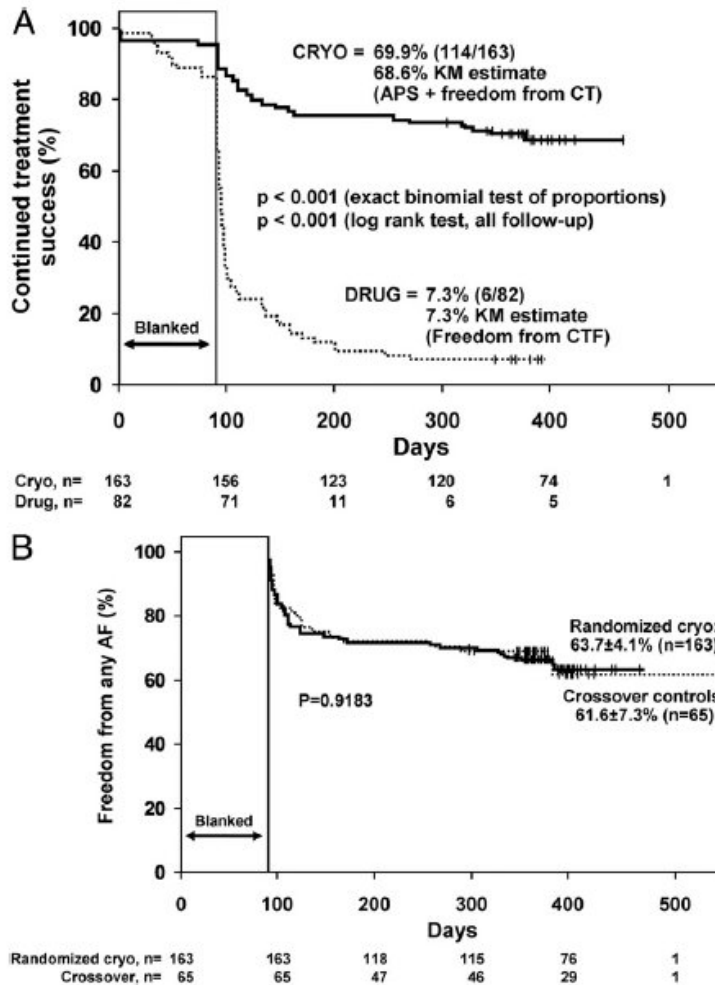


Figure 3 Procedural Success Given as Freedom From CTF as a Function of Time

(A) Intention-to-treat primary effectiveness endpoint for freedom from chronic treatment failure (CTF) between patients treated with cryoablation and those treated with drugs. (B) Freedom from any AF between the on-treatment cryoablation and drug-treated patients. KM = Kaplan-Meier estimates; OR = odds ratio.

PVI: 91%

23 and 28
mm CB-I

Complications in 229
pts ablated:
29 phrenic nerve palsy
25 rapidly resolved

RESULTS OF PIVOTAL STOP-AF TRIAL FDA APPROVED THE CB-I FOR PAROXYSMAL ATRIAL FIBRILLATION

Medtronic Receives FDA Approval for First and Only Cryoballoon Ablation Treatment in the U.S. for Paroxysmal Atrial Fibrillation

December 17, 2010 6:33 PM ET

New Arctic Front® Cardiac CryoAblation Catheter System Reduces Symptoms for Patients with Common Heart Rhythm Disorder

MINNEAPOLIS – December 17, 2010 – Medtronic, Inc. (NYSE:MDT) today announced that the U.S. Food and Drug Administration (FDA) has approved its Arctic Front® Cardiac CryoAblation Catheter system, the first and only Cryoballoon in the United States indicated for the treatment of drug refractory paroxysmal atrial fibrillation (PAF). The Cryoballoon treatment involves a minimally-invasive procedure that efficiently creates circumferential lesions around the pulmonary vein, which is the source of erratic electrical signals that cause the irregular heartbeat.

The FDA approval of the Arctic Front System was based on the pivotal STOP AF (Sustained Treatment of Paroxysmal Atrial Fibrillation) trial, which demonstrated the safety and efficacy of the device in treating and eradicating paroxysmal atrial fibrillation. The study showed that 69.9 percent of patients treated with Arctic Front were free from atrial fibrillation at one year, compared to 7.3 percent of patients treated with drug therapy only. The study also demonstrated that treatment with the device is safe, with limited procedure-related adverse events (3.1 percent), and patients enrolled in the study displayed a significant reduction of symptoms, a decrease in the use of drug therapy and substantial improvements in both physical and mental quality-of-life factors.

ANDRADE META-ANALYSIS: 19 studies, 974 pts 98.8% THE ACUTE PROCEDURAL SUCCESS



Andrade et al Cryoballoon Ablation for Atrial Fibrillation

Andrade J G et al, Heart rhythm 2011; 8:1444-1451

1447

1 year freedom from AF

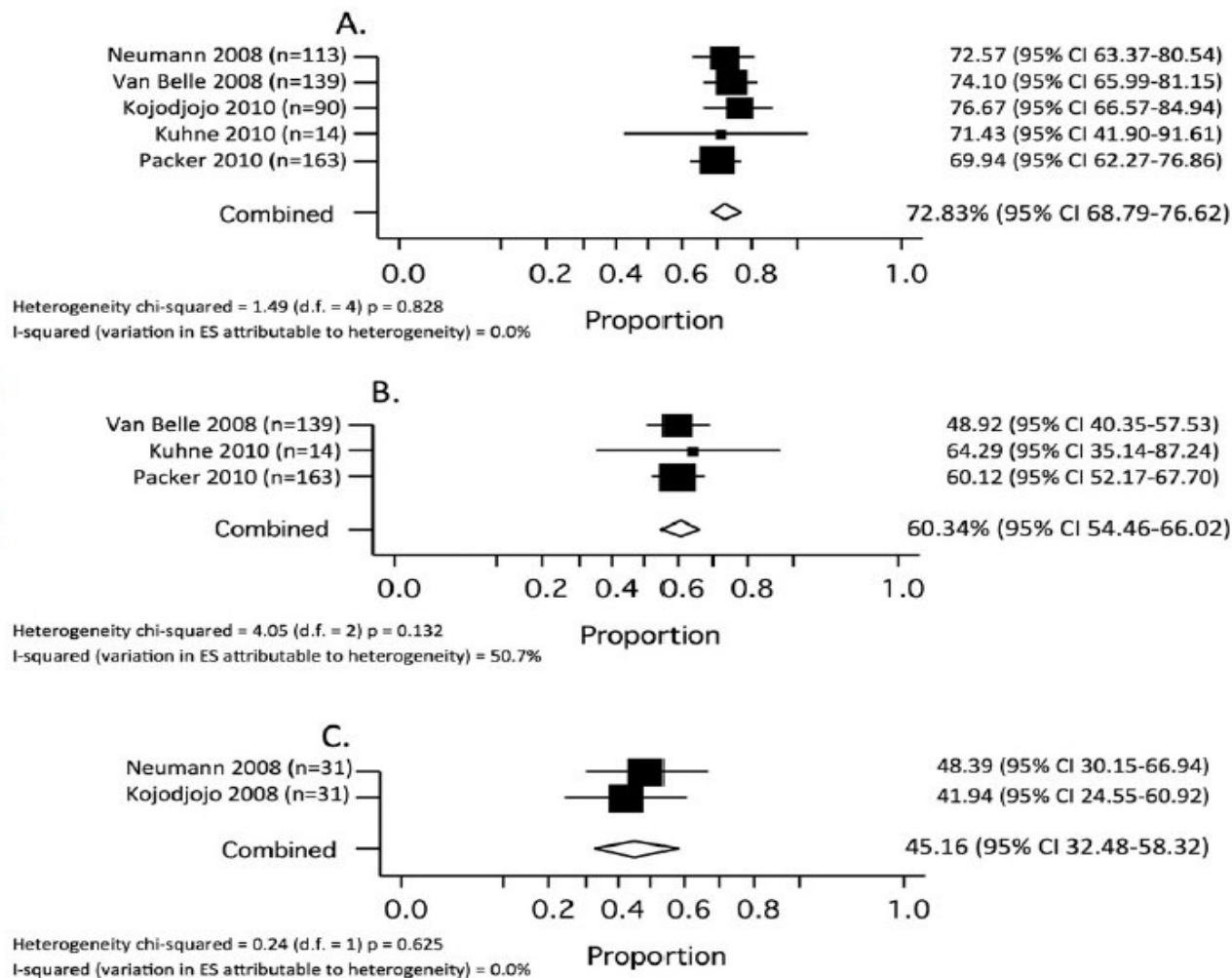


Figure 3 One-year freedom from recurrent atrial fibrillation (AF). **A:** Patients with paroxysmal AF after a 3-month blanking period. **B:** Patients with paroxysmal AF without a 3-month blanking period. **C:** Patients with persistent AF after a 3-month blanking period. CI = confidence interval; ES = effect size.

2012 HRS/EHRA/ECAS Expert Consensus Statement on Catheter and Surgical Ablation of Atrial Fibrillation: Recommendations for Patient Selection, Procedural Techniques, Patient Management and Follow-up, Definitions, Endpoints, and Research Trial Design

Table 2 Consensus indications for catheter and surgical ablation of AF

Indications for catheter ablation of AF	Class	Level
Symptomatic AF refractory or intolerant to at least one Class 1 or 3 antiarrhythmic medication		
Paroxysmal: Catheter ablation is recommended*	I	A
Persistent: Catheter ablation is reasonable	IIa	B
Longstanding Persistent: Catheter ablation may be considered	IIb	B

Table 3 Recommendations regarding ablation technique

- Ablation strategies that target the PVs and/or PV antrum are the cornerstone for most AF ablation procedures.
- If the PVs are targeted, electrical isolation should be the goal.
- Achievement of electrical isolation requires, at a minimum, assessment and demonstration of entrance block into the PV.

2012 HRS/EHRA/ECAS Expert Consensus

TABLE 3: RECOMMENDATIONS REGARDING ABLATION TECHNIQUE

- Ablation strategies that target the PVs and/or PV antrum are the cornerstone for most AF ablation procedures.
- If the PVs are targeted, electrical isolation should be the goal.
- Achievement of electrical isolation requires, at a minimum, assessment and demonstration of entrance block into the PV.

“... point-by-point RF energy and Cryoballoon ablation are the two standard ablation systems used for catheter ablation of AF today . . .”

Medtronic Receives FDA Approval, CE Mark for Arctic Front Advance™ Cardiac Cryoballoon to Treat Atrial Fibrillation

August 24, 2012 6:08 PM ET

Next-Generation Technology Reinforces Safety and Efficacy While Improving Procedure Efficiency

MINNEAPOLIS – Aug. 24, 2012 – Medtronic, Inc. (NYSE:MDT) today announced that its Arctic Front Advance™ Cardiac Cryoballoon has received both U.S. Food and Drug Administration (FDA) approval and CE (*Conformité Européenne*) Mark for the treatment of paroxysmal atrial fibrillation (PAF). With the only cryoballoon system currently on the market worldwide, Medtronic's second-generation system provides a more efficient approach to treating PAF than point-by-point, radiofrequency (RF) ablation.

About the Arctic Front Advance System

The Arctic Front Advance Cardiac CryoAblation Catheter System is designed to be used with fluoroscopy and does not require the use of complex, three-dimensional mapping systems. The technologies currently offered in the system include:

- The Arctic Front Advance Cryoballoon, which inflates and fills with coolant to ablate the tissue where the pulmonary veins enter the left atrium;
- The FlexCath® Steerable Sheath, which helps deliver and position the cryocatheter in the left atrium;
- The Achieve® Mapping Catheter, an intra-cardiac electrophysiology recording catheter used to assess pulmonary vein isolation when treating paroxysmal atrial fibrillation;

IN 2012 CB-1 EVOLVED , CB-ARCTIC FRONT-2 BECAME AVAILABLE,
MAKING IMMEDIATELY OBSOLETE THE CB-I TECH
THE CORE DIFFERENCE BETWEEN CB-1 AND -2:
EQUATORIAL ONLY COOLING ZONE VS THE ENTIRE
DISTAL HALF OF BALLOON

Arash Aryana

Received: 5 April 2014 / Accepted: 29 July 2014

J Interv Card Electrophysiol

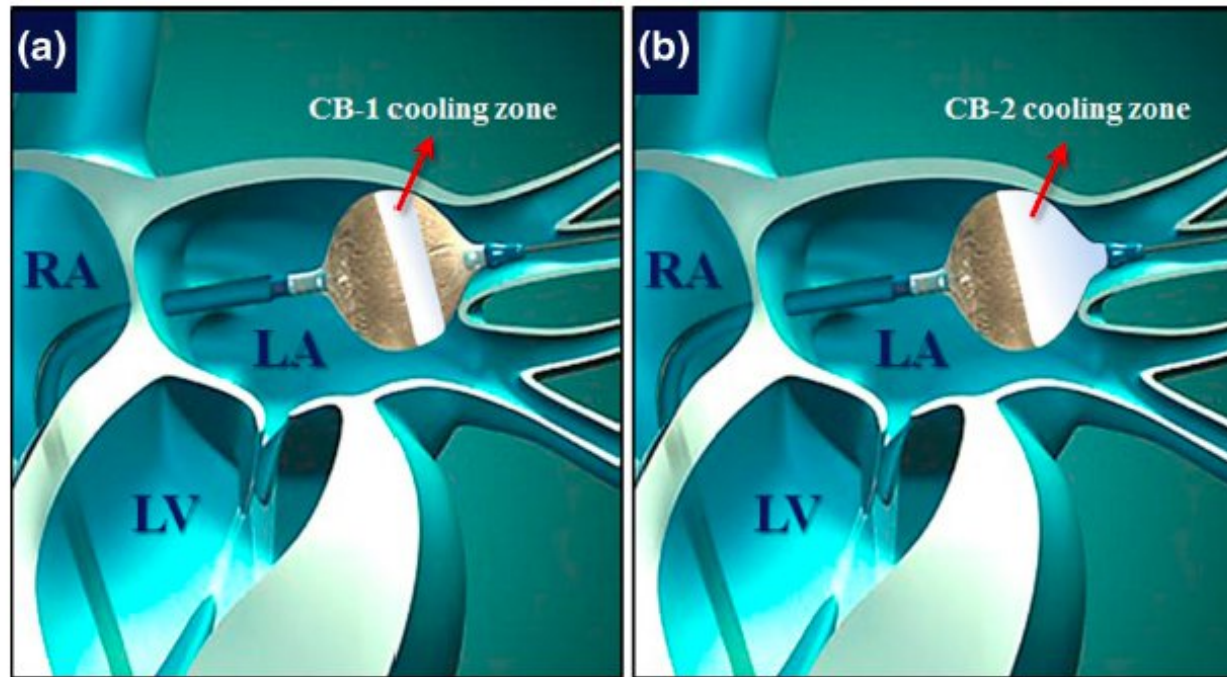
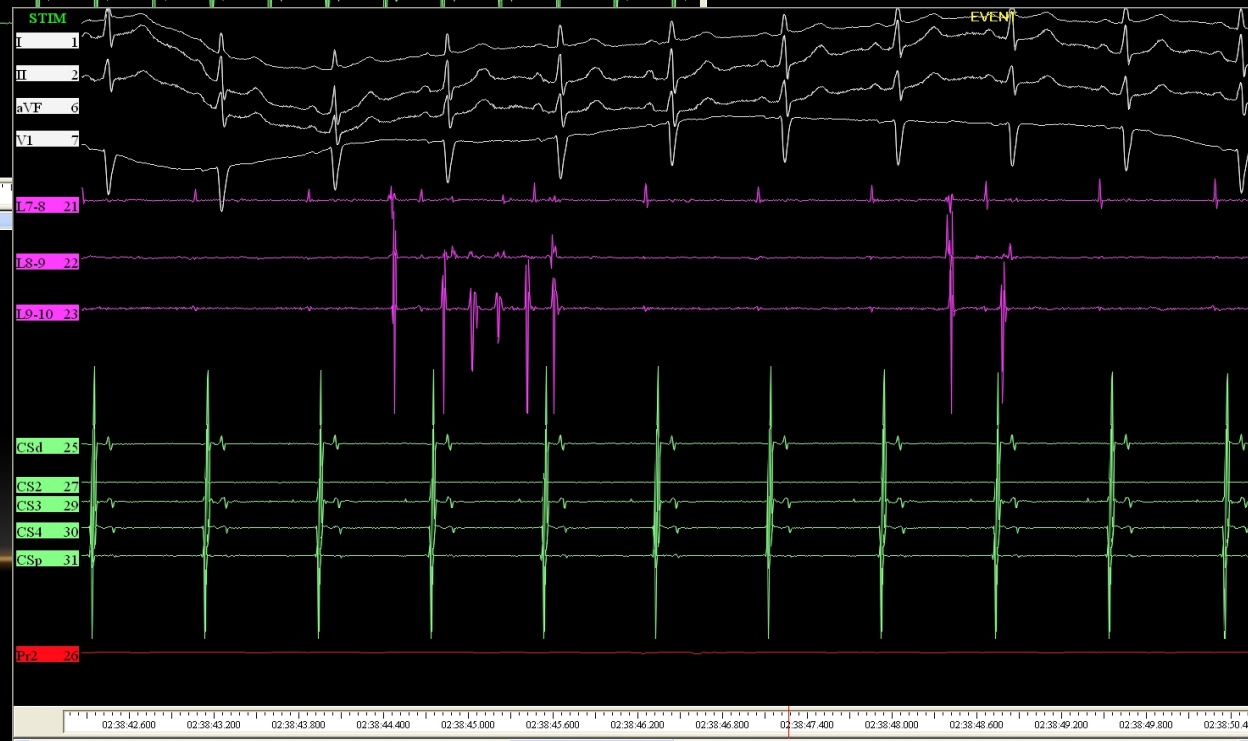


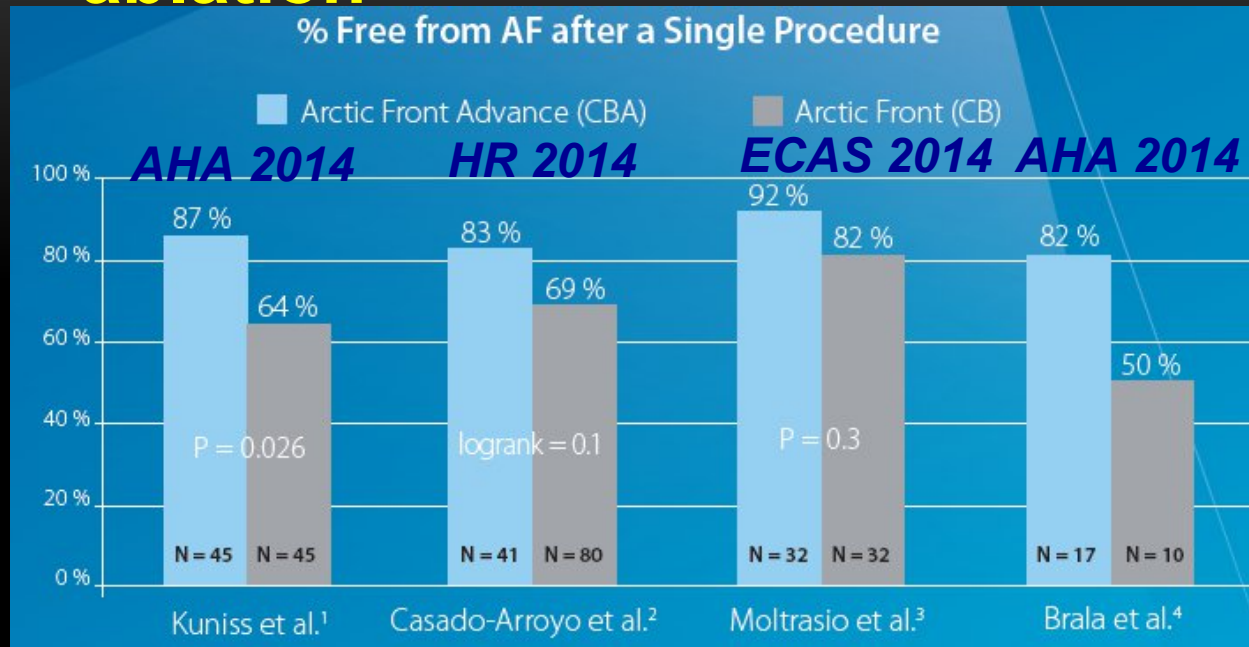
Fig. 1 The design of CB-1 and CB-2. **a** In CB-1, the cooling zone consists of a central equatorial band. Accordingly, optimal balloon positioning is key to ensure circumferential contact between PV antral tissue and the balloon cooling zone. In this illustration, the inferior segment of the left superior PV antrum is not in direct contact with the balloon

cooling zone. Ablation in this orientation will likely lead to incomplete PV isolation. **b** On the other hand, the CB-2 cooling zone spans over the entire distal half of its surface. This design modification offers a larger cooling surface area, minimizing the impact of balloon orientation on optimal tissue contact. *LA* left atrium, *LV* left ventricle, *RA* right atrium

Highly arrhythmogenic left common trunk (left panel) and RSPV (right panel) : dissociated PV firings within 48 sec freezing and 28 sec freezing respectively



Second generation vs first generation CB PV ablation

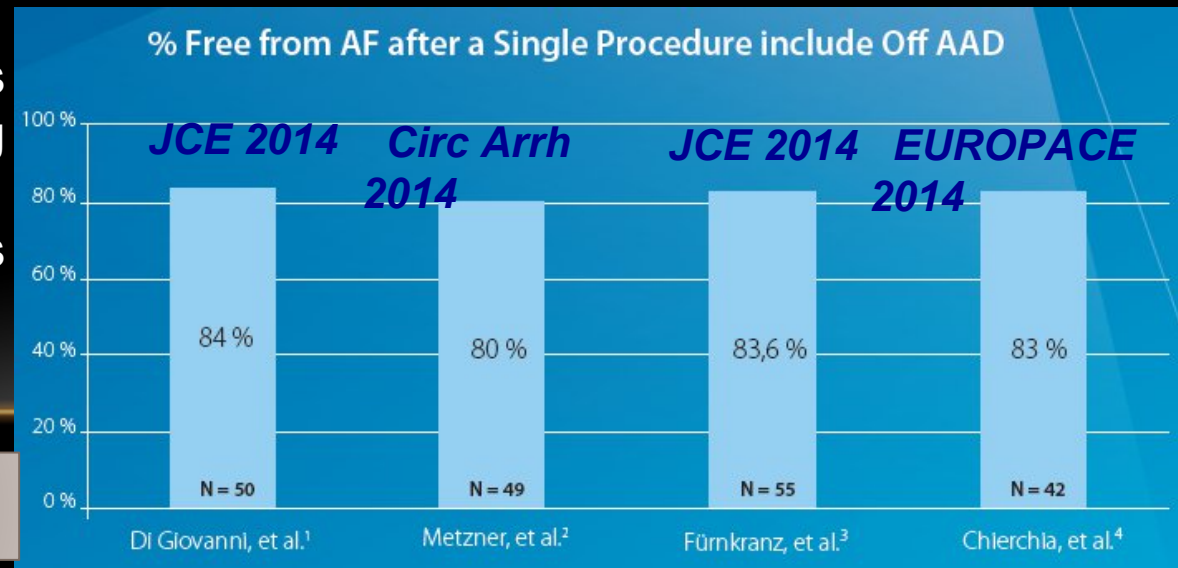


FU 6-12 MONTHS

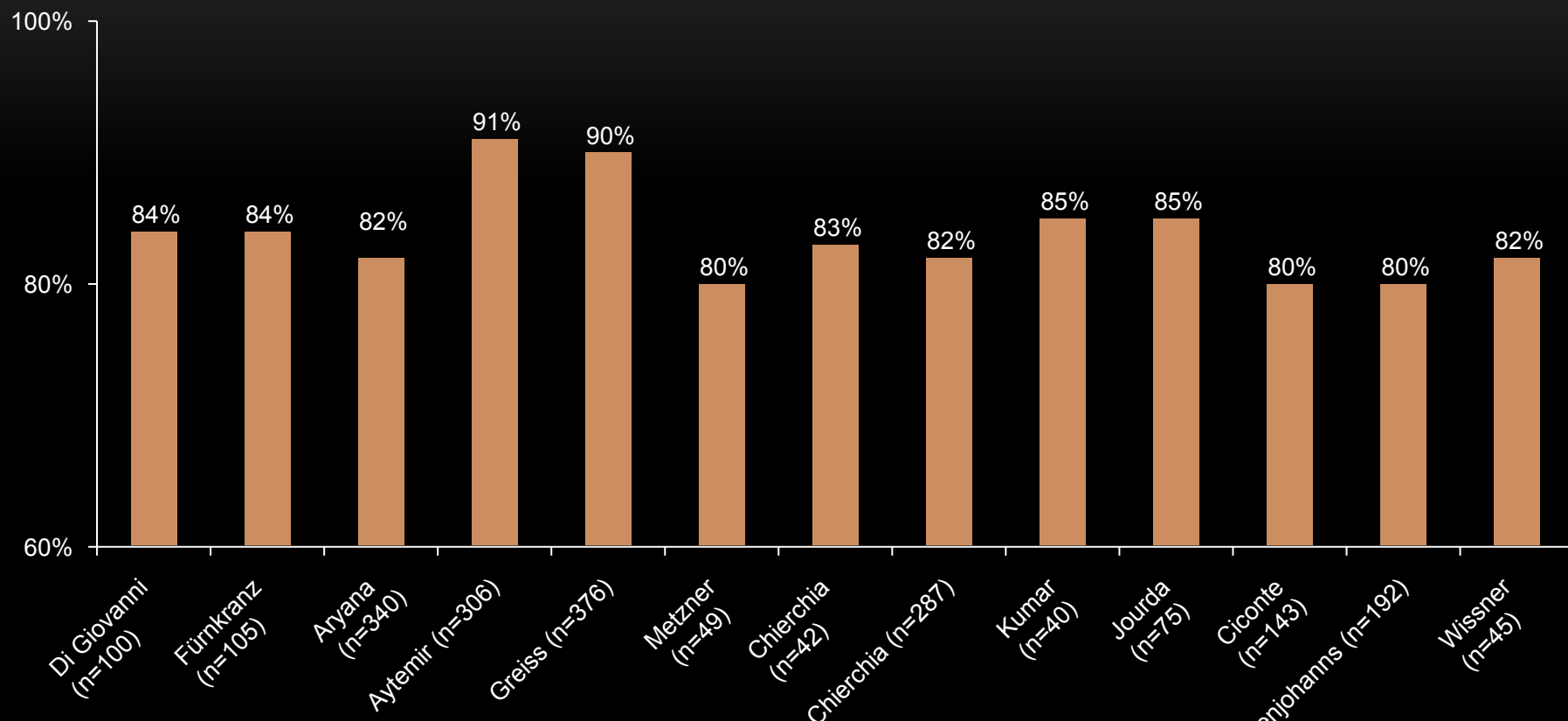
Munich
Bruxelles
Milan
Berlin

Bruxelles
Hamburg
Frankfurt
Bruxelles

FU 12 MONTHS



SINGLE PROCEDURE FREEDOM FROM AF, AT AND AFL ARCTIC FRONT ADVANCE™ CRYOBALLOON SINGLE CENTER PUBLISHED STUDIES



Arrhythmia Monitoring Methods and Definition of Procedure Success
(Freedom from AF Only or AF/AT/AFL) Varied Between Studies

Di Giovanni, et al. *J Cardiovasc Electrophysiol.* 2014; 25(8):834-9; Fürnkranz, et al. *Journal of Cardiovascular Electrophysiology.* 2014 ;25(8):840-4; Aryana, et al. *J Interv Card Electrophysiol.* 2014;41(2):177-186; Aytemir, et al. *Europace.* 2015;17(3):379-87; Greiss, et al. *PACE.* 2015 Jul;38(7):815-24; Metzner, et al. *Circ Arrhythm Electrophysiol.* 2014; 7(2):288-292; Chierchia, et al. *Europace.* 2014; 16(5):639-644; Chierchia, et al. *J Cardiovasc Electrophysiol.* 2015; In Press; 16(5):639-644; Kumar et al. *J Interv Card Electrophysiol.* 2014;41(1):91-7; Jourda, et al. *Europace.* 2015;17(2):225-31; Cicconte, et al. *Heart Rhythm.* 2015;12(4):673-80; Tebbenjohanns, et al. *Europace.* 2015; Wissner, et al. *Europace.* 2015 Aug;17(8):1236-40;

FIBRILLATION

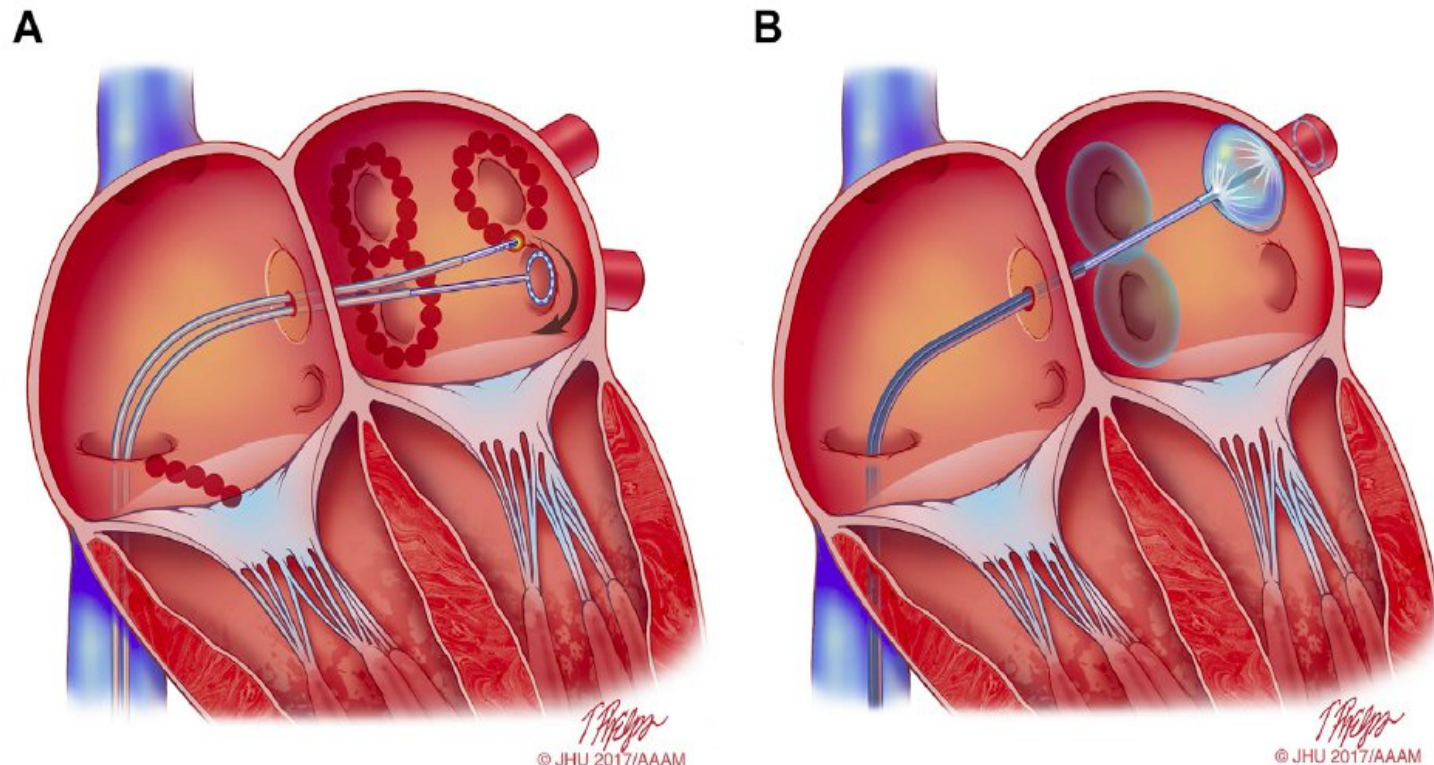


Figure 9 Schematic drawing showing catheter ablation of atrial fibrillation using either RF energy or cryoballoon AF ablation. **A:** Shows a typical wide area lesion set created using RF energy. Ablation lesions are delivered in a figure of eight pattern around the left and right PV veins. Also shown is a linear cavotricuspid isthmus lesion created for ablation of typical atrial flutter in a patient with a prior history of typical atrial flutter or inducible isthmus-dependent typical atrial flutter at the time of ablation. A multielectrode circular mapping catheter is positioned in the left inferior PV. **B:** Shows an ablation procedure using the cryoballoon system. Ablation lesions have been created surrounding the right PVs, and the cryoballoon ablation catheter is positioned in the left superior PV. A through the lumen multielectrode circular mapping catheter is positioned in the left superior PV. *Illustration: Tim Phelps © 2017 Johns Hopkins University, AAM.*

Verification of a novel atrial fibrillation cryoablation dosing algorithm guided by time-to-pulmonary vein isolation: Results from the Cryo-DOSING Study (Cryoballoon-ablation DOSING Based on the Assessment of Time-to-Effect and Pulmonary Vein Isolation Guidance)



Arash Aryana, MS, MD, FHRS,* David N. Kenigsberg, MD, FHRS,[†] Marcin Kowalski, MD, FHRS,[‡] Charles H. Koo, MD,[§] Hae W. Lim, PhD,[¶] Padraig Gearoid O'Neill, MD, FHRS,* Mark R. Bowers, MS, MD,* Robert B. Hokanson, BA,[¶] Kenneth A. Ellenbogen, MD, FHRS,^{||} Cryo-DOSING Investigators

(Heart Rhythm 2017;14:1319-1325)

755 pts included

Shorter procedural times (84 vs 145)

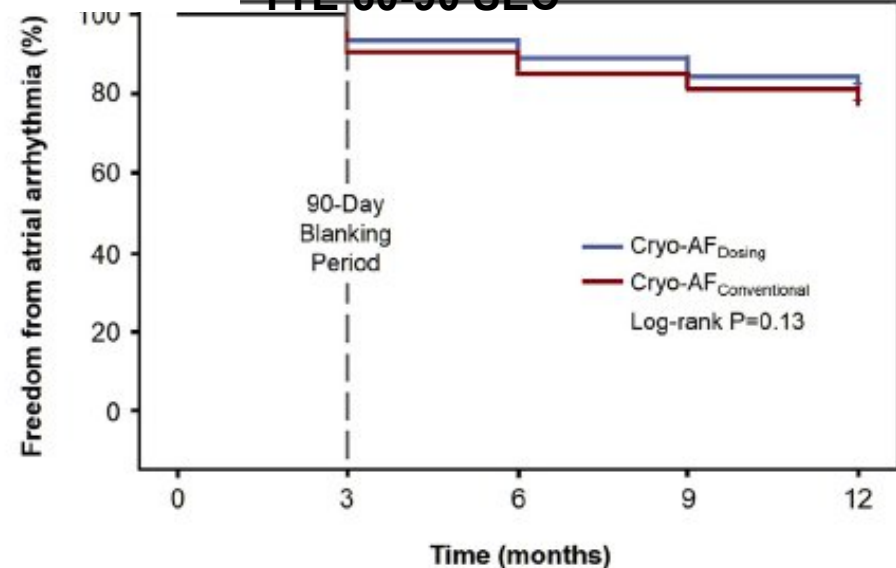
Shorter fluoroscopy times (13 vs 29 minutes)

Fewer complications (2 vs 2.7%)

With Time-to-Effect guided cryo

TWO-MINUTES FREEZE AFTER PVI IF TTE <60 SEC, SINGLE SHOT

TWO-MINUTES FREEZE AFTER PVI + TWO-MINUTES BONUS IF TTE 60-90 SEC



Number at Risk					
Cryo-AF _{Dosing}	355	355	331	316	299
Cryo-AF _{Conventional}	400	400	363	329	326

Figure 2 Kaplan-Meier estimates showing the cumulative freedom from all recurrent atrial arrhythmias after cryoballoon ablation of atrial fibrillation using the prespecified dosing protocol guided by time-to-pulmonary vein isolation (Cryo-AF_{Dosing}) vs the conventional, nonstandardized approach (Cryo-AF_{Conventional}). Freedom from all recurrent atrial arrhythmias did not differ between the 2 groups when compared by log-rank testing ($P = .13$).

Is less more? Impact of different ablation protocols on periprocedural complications in second-generation cryoballoon based pulmonary vein isolation

Laura Rottner^{1†}, Thomas Fink^{1†}, Christian-Hendrik Heeger¹, Michael Schlüter², Britta Goldmann³, Christine Lemes¹, Tilman Maurer¹, Bruno Reißmann¹, Enida Rexha¹, Johannes Riedl¹, Francesco Santoro¹, Peter Wohlmuth², Shibu Mathew¹, Christian Sohns¹, Feifan Ouyang¹, Karl-Heinz Kuck¹, and Andreas Metzner^{1*}

¹Department of Cardiology, Asklepios Klinik St Georg, Lohmühlenstraße 5, Hamburg 20099, Germany; ²Asklepios Proresearch, Asklepios Klinik St. Georg, Lohmühlenstraße 5, 20099 Hamburg, Germany; and ³Department of Cardiology, Asklepios Klinik Asklepios Klinik Harburg, Eißendorfer Pferdeweg 52, Harburg, Hamburg 21075, Germany

Received 14 March 2017; editorial decision 8 May 2017; accepted 8 June 2017

Incidence of complications significantly lower with Time-To-Effect guided ablation protocol: 563 pts

120 SECONDS

Europace (2017) 00, 1–9
doi:10.1093/europace/eux219

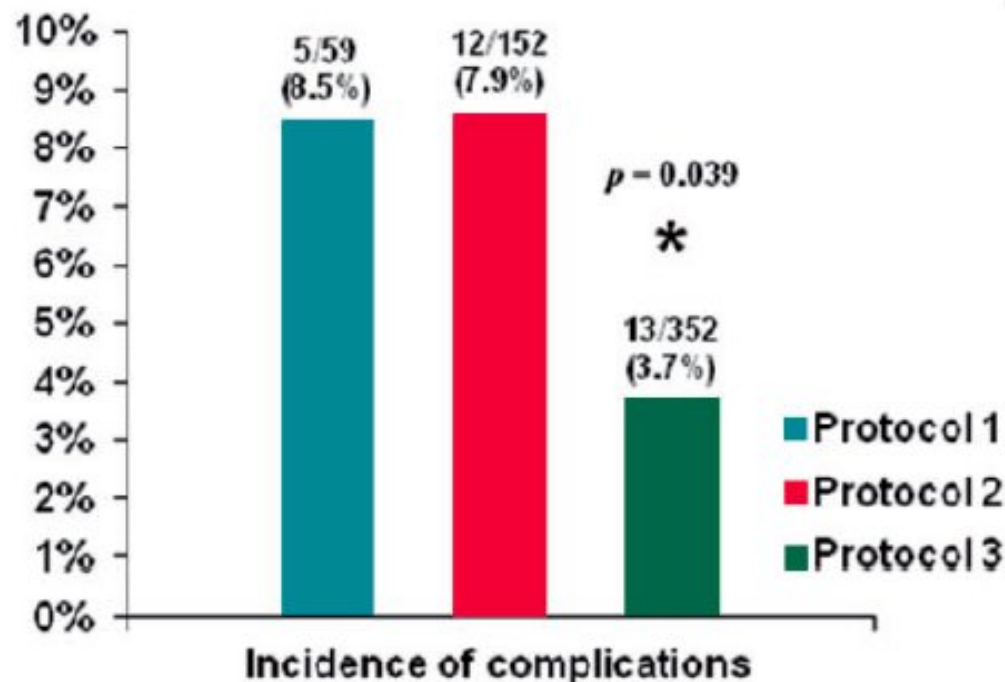


Figure 2 Incidence of complications with different ablation protocols. Protocol #1: a fixed freeze-cycle duration of 240 s, followed by an additional bonus-freeze of 240 s after successful PVI. Protocol #2: a fixed freeze-cycle of 240 s without a bonus freeze-cycle after documentation of PVI. Protocol #3: a 'time-to-effect' guided ablation strategy; after documentation of PVI the freeze-cycle was prolonged for additional 120 s. If no real-time PV signal recording could be obtained, a standard freeze-cycle of 180 sec. was applied. No bonus freeze-cycle was applied. *Statistically significant, $P = 0.0209$.

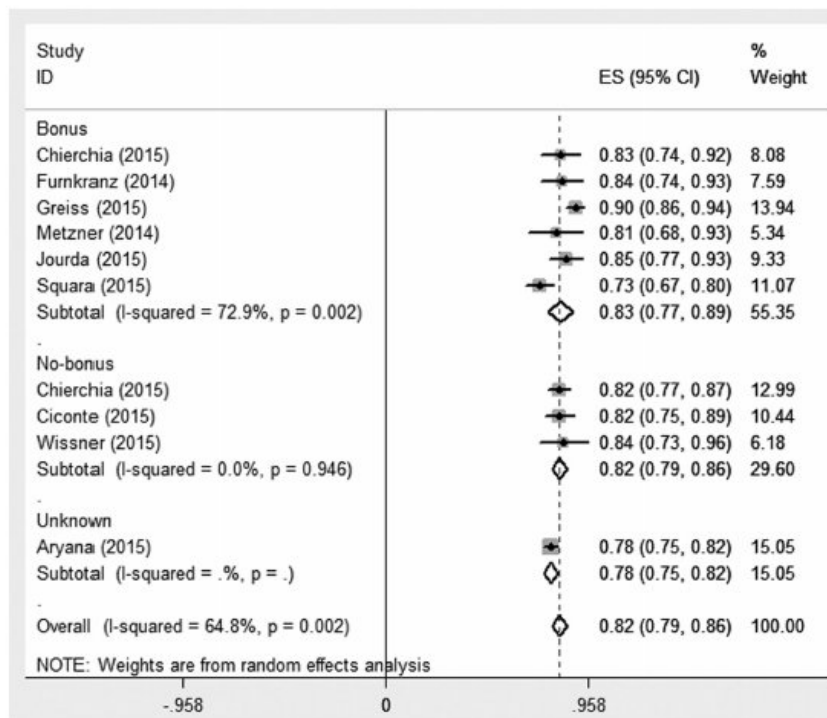


Figure 3. Forest plot and meta-analysis of 1-year clinical success rates in paroxysmal atrial fibrillation patients.

paroxysmal

No difference between
bonus or no bonus-freeze
for either paroxysmal or
persistent AF

PACE, 2016

One-Year Clinical Outcome of Pulmonary Vein Isolation Using the Second-Generation Cryoballoon: A Meta-Analysis

XIN HE, M.D.,* YILI CHEN, Ph.D.,* YUE ZHOU, M.S.,* YIYI HUANG, M.S.,† and JIANGUI HE, Ph.D.*

182

February 2016

PACE, Vol. 39

2363 pts

SECOND-GENERATION CRYOBALLOON AND META-ANALYSIS

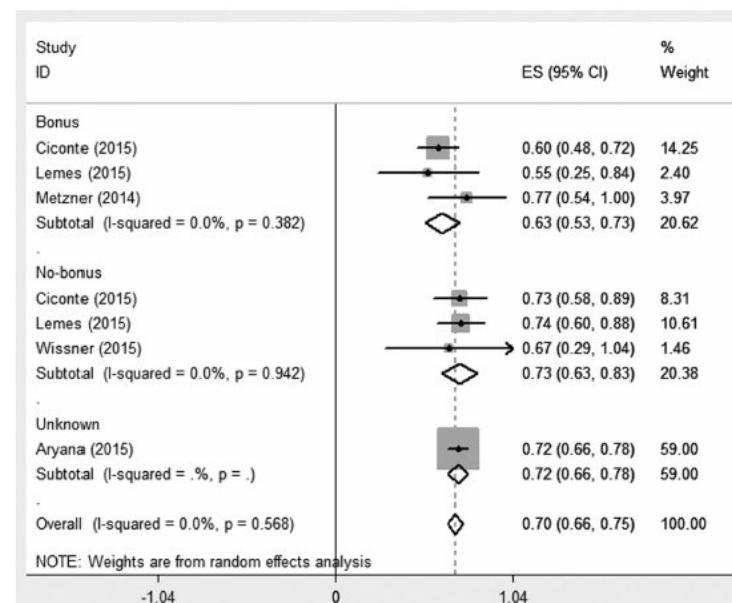


Figure 4. Forest plot and meta-analysis of 1-year clinical success rates in persistent atrial fibrillation patients.

persistent

European Heart Journal Advance Access published July 5, 2016



European Heart Journal
doi:10.1093/eurheartj/ehw285

FASTTRACK CLINICAL RESEARCH

Atrial fibrillation

ORIGINAL RESEARCH



Cryoballoon
for symptomatic
paroxysmal atrial
fibrillation: impact on
quality of life

Karl-Heinz Kuck
Feifan Ouyang
Thomas A. B. Alpert
Christian S. Vittinghoff
Investigators

The Impact of Cryoballoon Versus Radiofrequency Ablation for Paroxysmal Atrial Fibrillation on Healthcare Utilization and Costs: An Economic Analysis From the FIRE AND ICE Trial

K. R. Julian Chun, MD; Josep Brugada, MD; Arif Elvan, MD; Laszlo Gellér, MD; Matthias Busch, MD; Alberto Barrera, MD; Richard J. Schilling, MD; Matthew R. Reynolds, MD; Robert B. Hokanson, BA; Reece Holbrook, BSEE; Benedict Brown, MBA; Michael Schlüter, PhD; Karl-Heinz Kuck, MD; for the FIRE AND ICE Investigators*

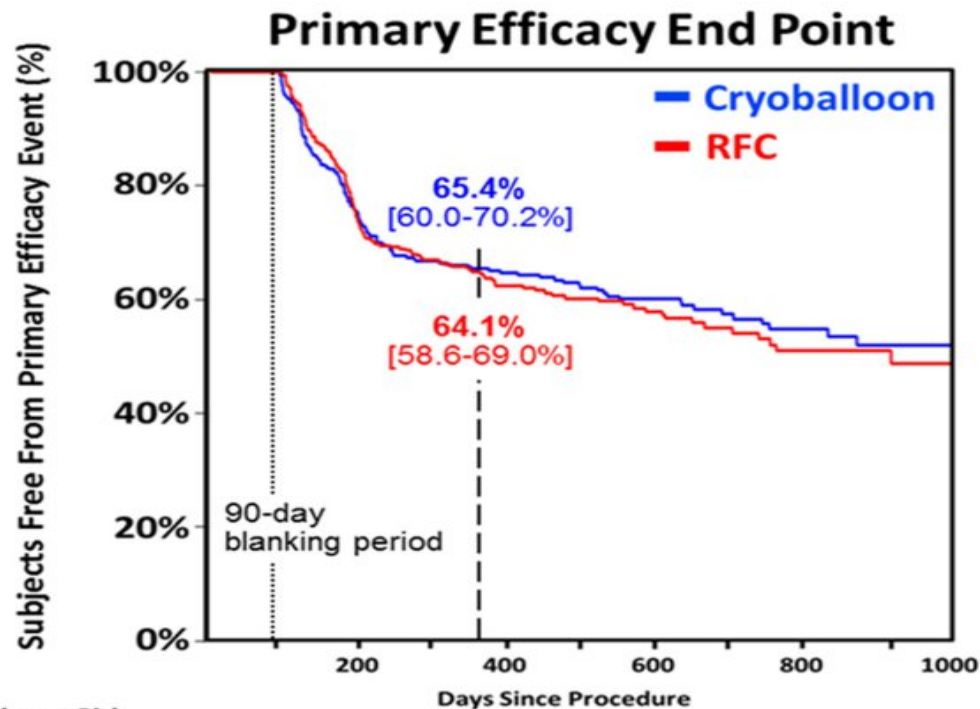
Background—This study sought to assess payer costs following cryoballoon or radiofrequency current (RFC) catheter ablation of paroxysmal atrial fibrillation in the randomized FIRE AND ICE trial.

Methods and Results—A trial period analysis of healthcare costs evaluated the impact of ablation modality (cryoballoon versus RFC) on differences in resource use and associated payer costs. Analyses were based on repeat interventions, rehospitalizations, and cardioversions during the trial, with unit costs based on 3 national healthcare systems (Germany [€], the United Kingdom [£], and the United States [\$]). Total payer costs were calculated by applying standard unit costs to hospital stays, using *International Classification of Diseases, 10th Revision* diagnoses and procedure codes that were mapped to country-specific diagnosis-related groups. Patients (N=750) randomized 1:1 to cryoballoon (n=374) or RFC (n=376) ablation were followed for a mean of 1.5 years. Resource use was lower in the cryoballoon than the RFC group (205 hospitalizations and/or interventions in 122 patients versus 268 events in 154 patients). The cost differences per patient in mean total payer costs during follow-up were €640, £364, and \$925 in favor of cryoballoon ablation ($P=0.012$, 0.013 , and 0.016 , respectively). This resulted in trial period total cost savings of €245 000, £140 000, and \$355 000.

Conclusions—When compared with RFC ablation, cryoballoon ablation was associated with a reduction in resource use and payer costs. In all 3 national healthcare systems analyzed, this reduction resulted in substantial trial period cost savings, primarily attributable to fewer repeat ablations and a reduction in cardiovascular rehospitalizations with cryoballoon ablation.

Clinical Trial Registration—URL: <http://www.clinicaltrials.gov>. Identifier: NCT01490814. (*J Am Heart Assoc.* 2017;6:e006043. DOI: 10.1161/JAHA.117.006043.)

MET



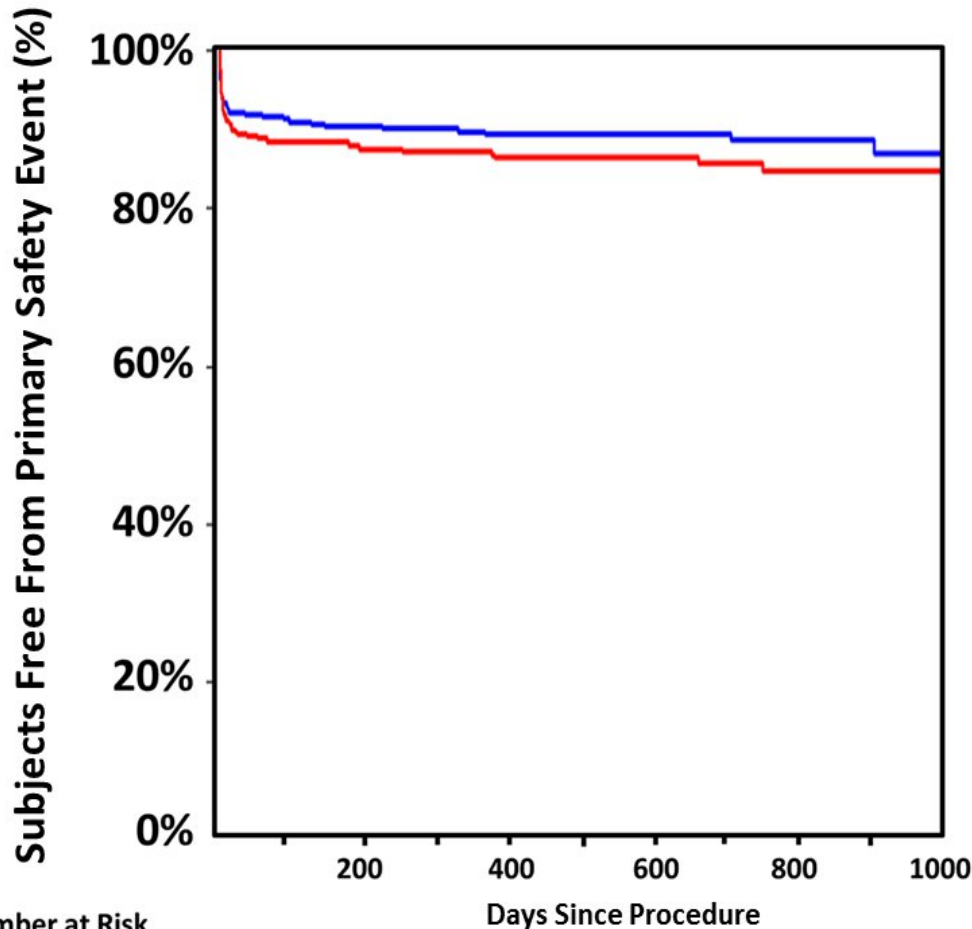
Number at Risk											
Cryoballoon	374	338	242	194	165	132	107	70	57	34	12
RFC	376	350	243	191	149	118	93	58	44	25	12

Efficacy End Point Type	Cryo (N=374)	RFC (N=376)
Recurrent atrial arrhythmia	80	87
Antiarrhythmic drug prescription	51	49
Re-ablation	7	7

Modified ITT analysis

- Non-inferiority hypothesis met
- HR [95% CI] = 0.96 [0.76-1.22];
- $p = 0.0004$
- Superiority test: $p = 0.74$

PRIMARY SAFETY ENDPOINT MET



Modified ITT analysis

HR [95% CI] = 0.78 [0.52-1.18]; p = 0.24

Safety Event Type	RFC (n=376)	Cryoballoon (n=374)
All-cause death*	0	2
All-cause stroke/TIA	2	2
Arrhythmia-related SAE	13	8
Non-arrhythmia-related SAE	36	28
Total	51	40

* Unrelated to treatment/device

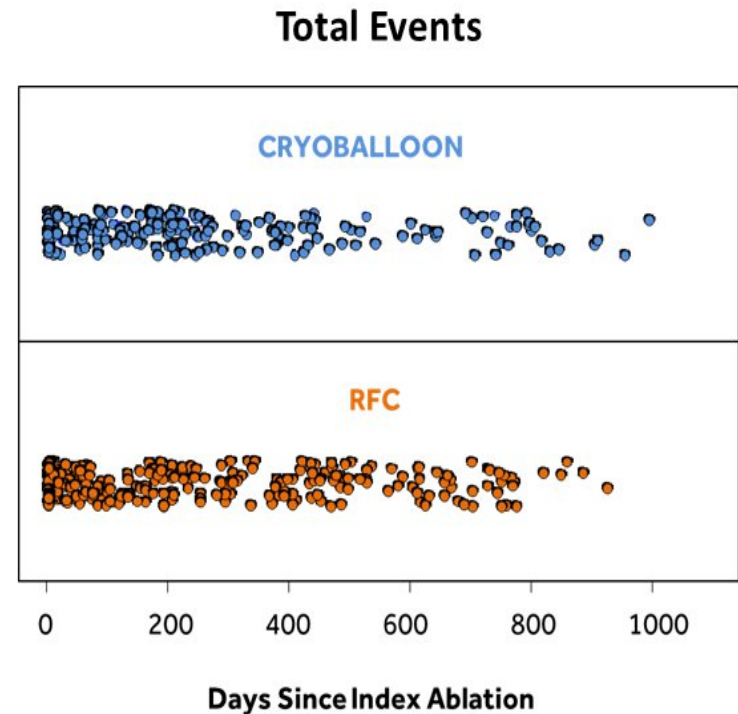
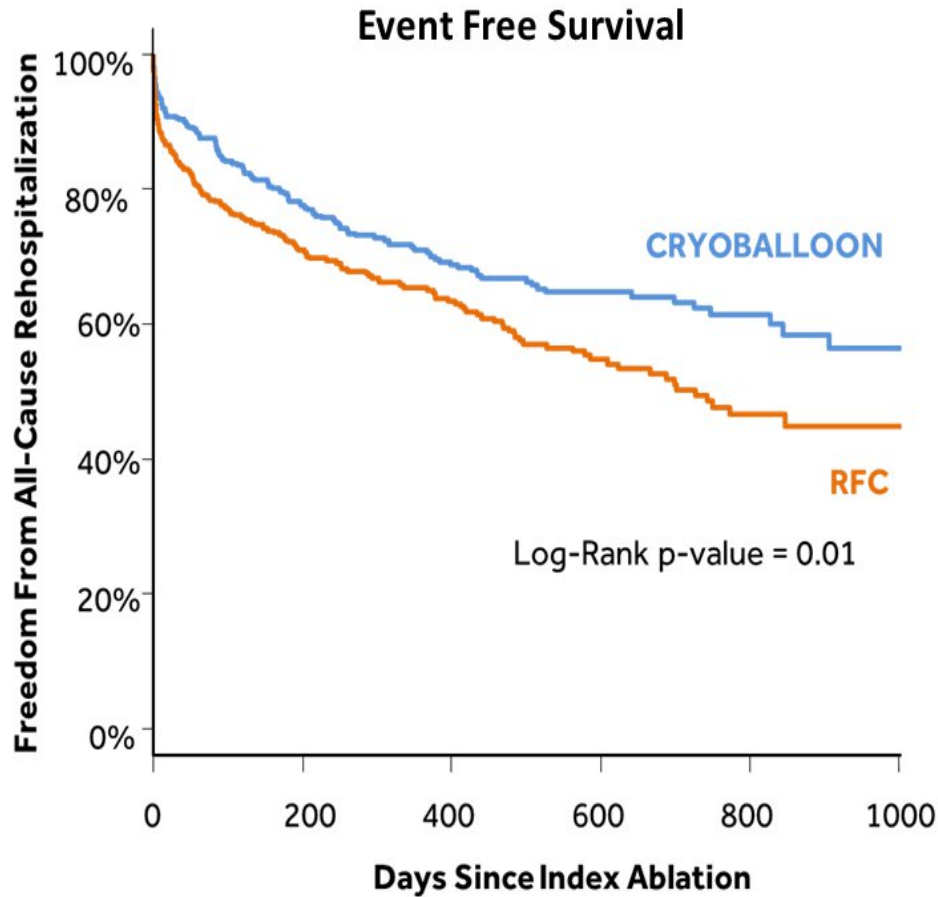
FIRE AND ICE, 2016
KUCK KH, ET AL. *EUR HEART J* (2016)

**in the Cryoballoon Group vs
Radiofrequency Group**

- 21% Fewer All-Cause Hospitalizations
- 34% Fewer CV Hospitalizations
- 33% Fewer Repeat Ablations
- 50% Fewer DC Cardioversions

FREEDOM FROM ALL-CAUSE HOSPITALIZATION

21% Fewer All-Cause Hospitalizations in the Cryoballoon Group vs Radiofrequency Group



Cryo: 210 events in 122 subjects (122/374; **32.6%**)

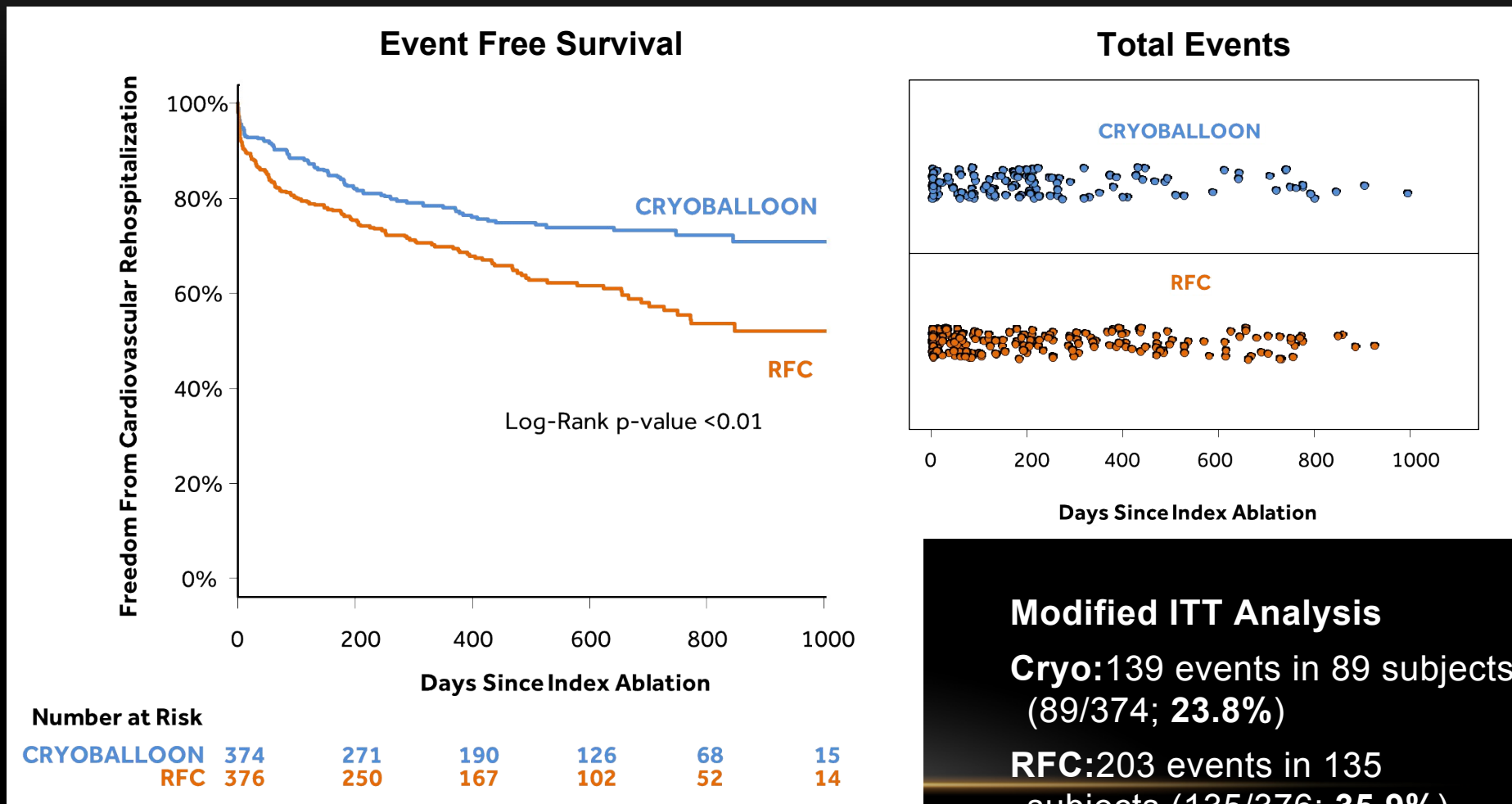
RFC: 267 events in 156 subjects (156/376; **41.5%**)

Number at Risk

CRYOBALLOON	374	257	174	113	56	13
RFC	376	235	157	90	43	10

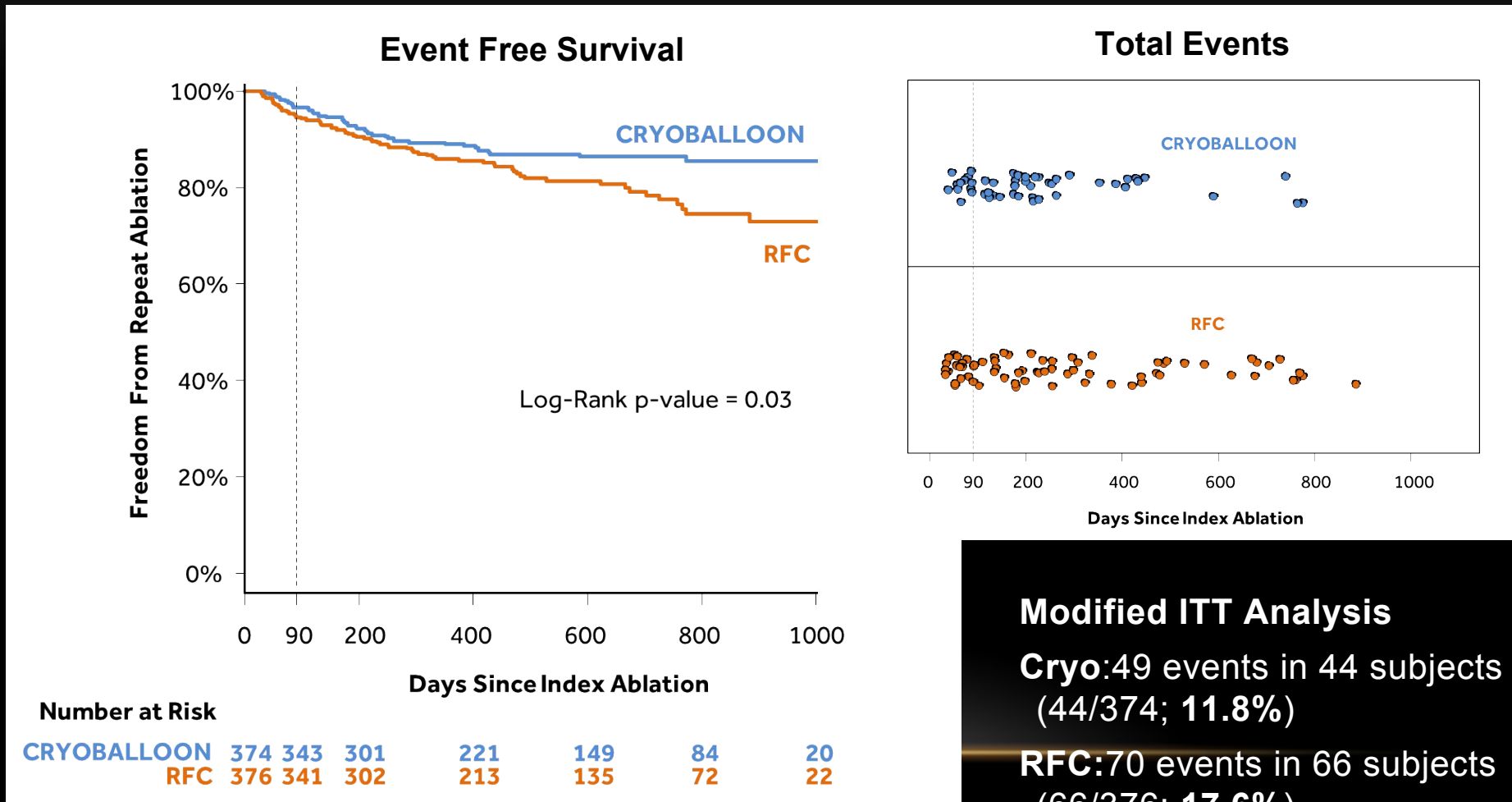
FREEDOM FROM CARDIOVASCULAR HOSPITALIZATION

34% Fewer CV Hospitalizations in the Cryoballoon Group vs Radiofrequency Group



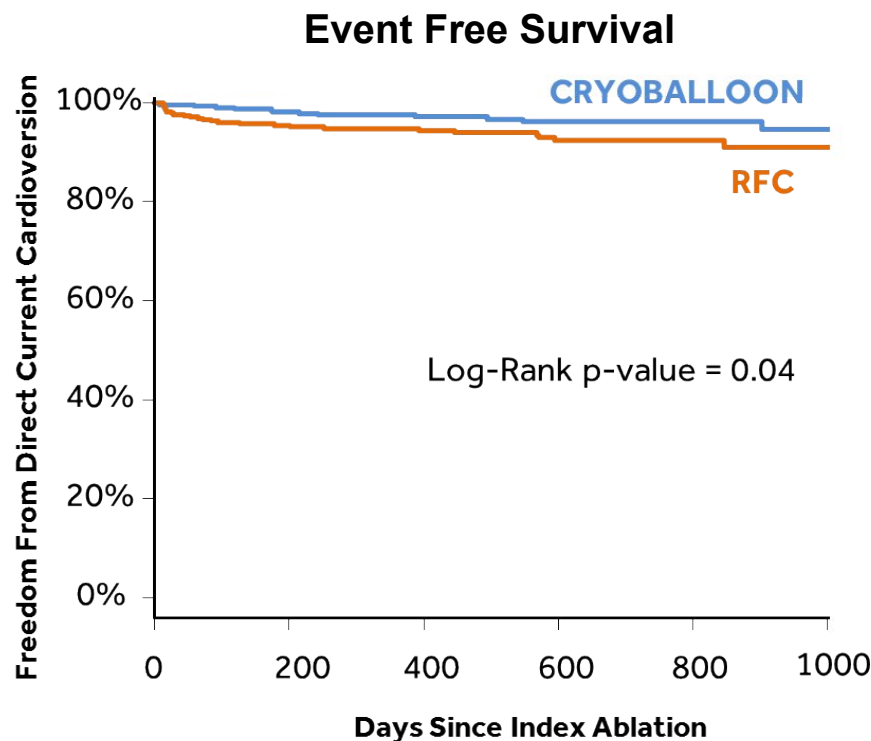
FREEDOM FROM REPEAT ABLATION

33% Fewer Repeat Ablations in the Cryoballoon Group vs Radiofrequency Group



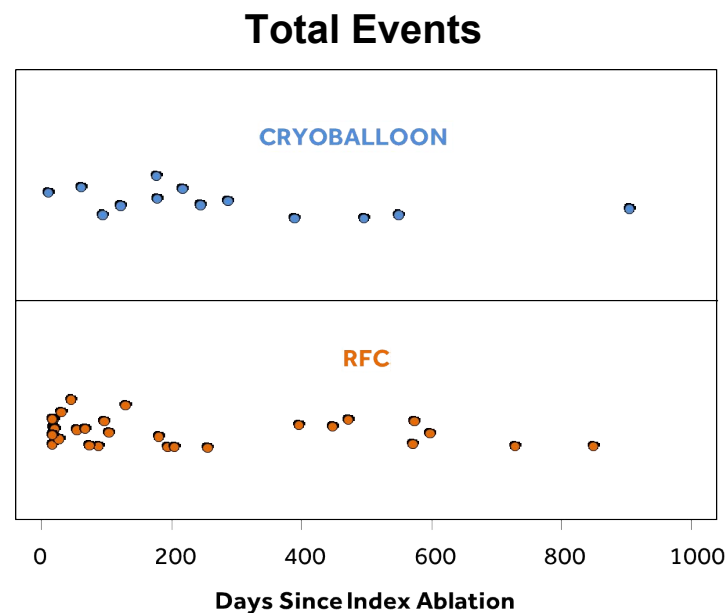
FREEDOM FROM DC CARDIOVERSION

50% Fewer DC Cardioversions in the Cryoballoon Group vs Radiofrequency Group



Number at Risk

CRYOBALLOON	374	321	247	170	100	24
RFC	376	320	235	162	96	30



Modified ITT Analysis

Cryo: 13 events in 12 subjects (12/374; **3.2%**)

RFC: 28 events in 24 subjects (24/376; **6.4%**)

Cryoablation vs. radiofrequency ablation for treatment of paroxysmal atrial fibrillation: a systematic review and meta-analysis

Yi-He Chen¹, Zhao-Yang Lu¹, Yin-Xiang¹, Jian-Wen Hou¹, Qian Wang¹, Hui Lin^{2*}, and Yi-Gang Li^{1*}

¹Department of Cardiology, Xinhua Hospital Affiliated to The Medical School of Shanghai Jiaotong University, 1665 Kongjiang Road, Shanghai 200092, China; and ²Department of Respiratory, The Second Affiliated Hospital of Wenzhou Medical University, Wenzhou 325027, China

Received 18 August 2016; accepted after revision 19 September 2016; online publish-ahead-of-print 8 January 2017

7.026 PIS

PAROXYSMAL
AF

FREEZE and Fire and
ICE included

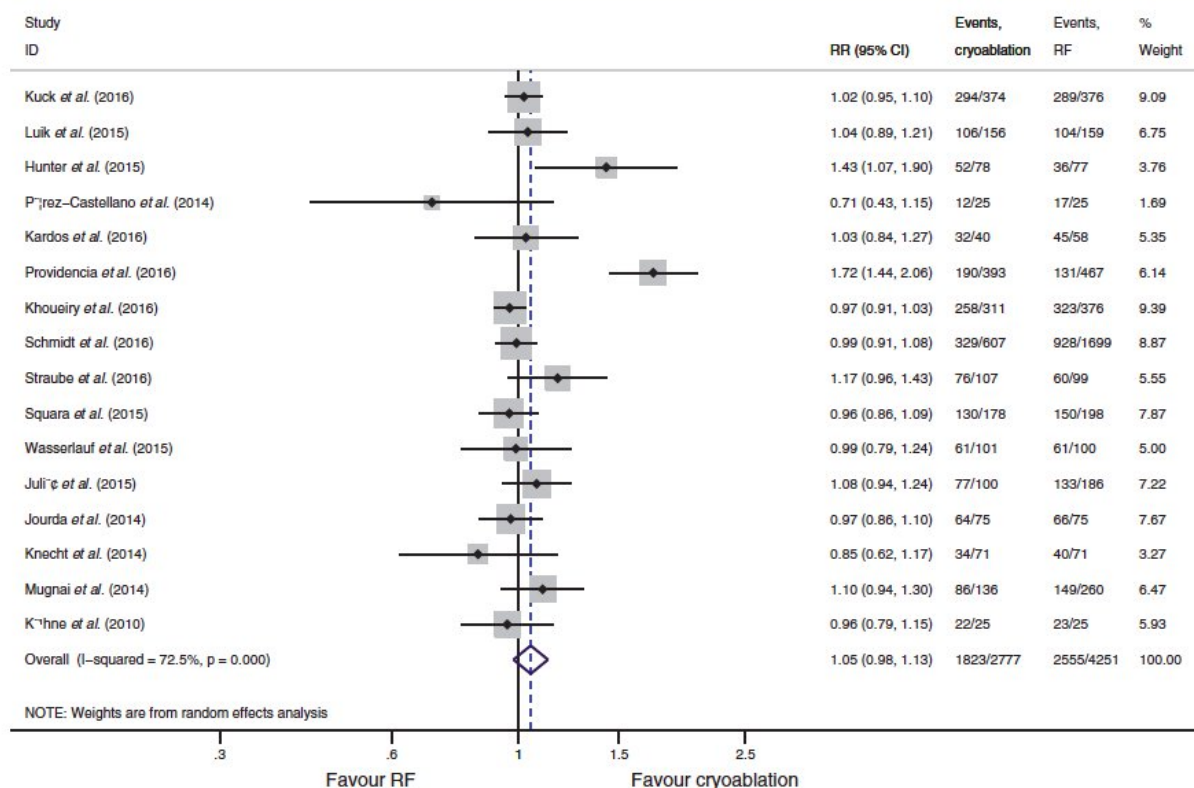


Figure 2 Forest plot of AF/atrial tachycardia-free survival for cryoablation vs. RF ablation.



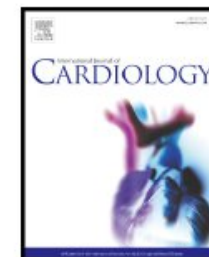
International Journal of Cardiology 272 (2018) 130–136



Contents lists available at ScienceDirect

International Journal of Cardiology

journal homepage: www.elsevier.com/locate/ijcard



Center experience does not influence long-term outcome and peri-procedural complications after cryoballoon ablation of paroxysmal atrial fibrillation: Data on 860 patients from the real-world multicenter observational project



Maurizio Landolina ^{a,*}, Giuseppe Arena ^b, Saverio Iacopino ^c, Roberto Verlato ^d, Paolo Pieragnoli ^e, Antonio Curnis ^f, Maurizio Lunati ^g, Werner Rauhe ^h, Gaetano Senatore ⁱ, Luigi Sciarra ^j, Giulio Molon ^k, Pietro Maria G. Agricola ^{a,l}, Luigi Padeletti ^{m,n}, Claudio Tondo ^o



Second versus fourth generation of cryoballoon catheters: The 1STOP real-world multicenter experience

Massimiliano Manfrin MD¹  | Roberto Verlato MD²  | Giuseppe Arena MD³ |
 Paolo Pieragnoli MD⁴ | Giulio Molon MD, FESC, FACC⁵ | Claudio Tondo MD, PhD⁶  |
 Giovanni Battista Perego MD⁷ | Giovanni Rovaris MD⁸ | Luigi Sciarra MD, PhD⁹  |
 Massimo Mantica MD¹⁰ | Riccardo Sacchi MD¹¹ | Danilo Ricciardi MD¹² |
 Massimiliano Marini MD¹³  | Saverio Iacopino MD¹⁴ 

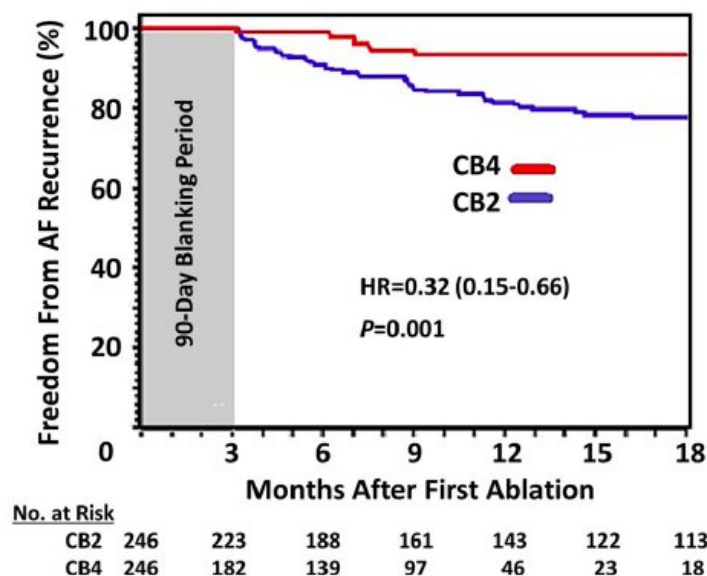


FIGURE 2 Freedom from AF recurrence by Kaplan–Meier estimate. In the CB2 group, the mean follow-duration was 22.6 ± 16.5 months, and in the CB4 group, it was 8.0 ± 5.1 months ($p < .001$) [Color figure can be viewed at [wileyonlinelibrary.com](https://onlinelibrary.wiley.com)]

CRYOABLATION FOR PERSISTENT ATRIAL FIBRILLATION ABLATION



Europace (2015) 17, 559–565
doi:10.1093/europace/eu3350

CLINICAL RESEARCH

Ablation for atrial fibrillation

Circumferential pulmonary vein isolation as index procedure for persistent atrial fibrillation: a comparison between radiofrequency catheter ablation and second-generation cryoballoon ablation

Giuseppe Ciconte[†], Giannis Baltogiannis[†], Carlo de Asmundis, Juan Seira, Giulio Conte, Giacomo Di Giovanni, Yukio Saitoh, Ghazala Irfan, Giacomo Mugnai, Burak Hunuk, Gian-Battista Chierchia[‡], and Pedro Brugada[‡]

Heart Rhythm Management Centre, UZ Brussel-VUB, Vrije Universiteit Brussel, 101 Laarbeeklaan, 1090 Brussels, Belgium

Received 26 September 2014; accepted after revision 10 November 2014; online publication ahead of print 12 January 2015

Aims

To assess the 1-year efficacy of pulmonary vein isolation (PVI) as index procedure for persistent atrial fibrillation (PersAF) comparing conventional radiofrequency irrigated-tip catheter ablation (RFCA) using contact-force technology and ablation using the second-generation cryoballoon (CB-AdvA).

Methods and results

One hundred consecutive patients (74 male, 74%; mean age 62.4 ± 9.6 years) with drug-refractory PersAF undergoing PVI using RFCA and CB-AdvA were enrolled. Follow-up was based on outpatient clinic visits including Holter-electrocardiograms. Recurrence of atrial tachyarrhythmias (ATas) was defined as a symptomatic or documented episode >30 s. Among 100 patients, 50 underwent RFCA whereas 50 CB-AdvA. Mean procedure and fluoroscopy times were 90.5 ± 41.7 vs. 140.2 ± 46.9 min and 14.5 ± 6.6 vs. 19.8 ± 6.8 min in the CB-Adv and in the RFCA group, respectively ($P < 0.01$). At 1 year follow-up, after a 3 months blanking period (BP), freedom from ATas off-drugs after a single procedure was 60% (28/50 patients) in the CB-Adv and 56% (27/50 patients) in the RFCA group ($P = 0.71$). Multivariate analysis demonstrated that PersAF duration ($P = 0.01$) and relapses during BP ($P = 0.02$) were independent predictors of ATa recurrences following the index procedure.

Conclusion

Freedom from ATas following PersAF ablation with RFCA and CB-Adv is comparable at 1 year follow-up after a single procedure. Ablation with the CB-Adv is associated with shorter procedure time and radiation exposure as compared with RFCA. Atrial tachyarrhythmias occurrence during BP and longer time of PersAF seem to be significant predictors of arrhythmia recurrences after the index procedure.

Keywords

Radiofrequency catheter ablation; • Cryoballoon ablation • Second generation cryoballoon • Persistent atrial fibrillation • Pulmonary vein isolation • One year follow-up

J Interv Card Electrophysiol (2016) 47:133–142
DOI 10.1007/s10840-016-0138-1



MULTIMEDIA REPORT

Outcomes after cryoballoon or radiofrequency ablation for persistent atrial fibrillation: a multicentric propensity-score matched study

Serge Boveda¹ · Rui Providência² · Pascal Defaye³ · Dominique Pavin⁴ · Jean-Pierre Ceburon⁵ · Frederic Ansme⁶ · Franck Halimi⁷ · Ziad Khoueiry⁸ · Nicolas Combes¹ · Stéphane Combes¹ · Sophie Jacob¹ · Jean-Paul Albenque¹ · Pedro Sousa¹

Received: 18 March 2016 / Accepted: 20 April 2016 / Published online: 18 May 2016
© Springer Science+Business Media New York 2016

Abstract

Purpose Recent data show no benefit of additional ablation beyond pulmonary vein isolation (PVI) in persistent atrial fibrillation (AF). Evidence suggests that radiofrequency energy (RF) and cryoballoon (CRYO) have comparable efficacy for PVI. We aimed to assess the outcomes after a single catheter ablation procedure, comparing PVI using CRYO vs. RF ablation for PVI plus additional ablation in a cohort of patients with persistent AF.

Methods In this prospective multicenter propensity score-matched comparison, 59 consecutive patients undergoing CRYO ablation of persistent AF were matched to 59 patients treated with RF from November 2010 to June 2012.

Electronic supplementary material The online version of this article (doi:10.1007/s10840-016-0138-1) contains supplementary material, which is available to authorized users.

✉ Serge Boveda
s.boveda@clinique-pasteur.com

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² Barts Heart Centre, Barts Health NHS Trust, London, UK

³ University Hospital Michallon, Grenoble, France

Results During a mean follow-up of 15.6 ± 11.5 months, 43.2 % of patients presented atrial arrhythmia relapse after a blanking period of 3 months, which was comparable between the two groups (40.7 % in CRYO vs. 45.8 % in RF, Log rank $P = 0.14$; HR = 0.67, 95 % CI 0.38–1.16, $P = 0.15$), despite the fact that 52.5 % of RF patients add additional complex fractionated atrial electrogram ablation, as well as left atrial linear ablation in over two-thirds (roof line in 67.8 % and mitral isthmus in 32.2 %). On multivariate Cox regression, only AF duration in years (HR = 1.10, 95 % CI 1.01–1.10, $P = 0.04$) was a predictor of relapse. Patients undergoing RF ablation presented a numerically, but non-significantly, lower complication rate (6.8 vs 10.2 %, $P = 0.51$).

Conclusion In our multicenter experience, freedom from atrial arrhythmias was comparable among matched patients treated with CRYO and RF, despite non-significant trends in favor of RF in terms of complications, at the cost of longer procedure times.

Keywords Atrial fibrillation · Pulmonary vein isolation · Arrhythmia relapse · Cryoballoon ablation · Radiofrequency ablation

2015, 50
pts

60% AT freedom at 12
months

2016, 50 pts

59.3 % AT freedom at 15
months

Pulmonary vein isolation cryoablation for patients with persistent and long-standing persistent atrial fibrillation: Clinical outcomes from the real-world multicenter observational project



Claudio Tondo, MD, PhD, * Saverio Iacopino, MD, † Paolo Pieragnoli, MD, ‡ Giulio Molon, MD, § Roberto Verlato, MD, || Antonio Curnis, MD, ¶ Maurizio Landolina, MD, # Giuseppe Allocca, MD, ** Giuseppe Arena, MD, †† Gaetano Fassini, MD, * Luigi Sciarra, MD, ‡‡ Mario Luzi, MD, §§ Massimiliano Manfrin, MD, |||| Luigi Padeletti, MD, ¶¶ on behalf of ClinicalService 1STOP Project Investigators

*From the *Heart Rhythm Center at Monzino Cardiac Center, IRCCS Department of Clinical Sciences and Community Health, University of Milan, Milan, Italy, †GVM Care & Research Group, Cotignola, Italy, ‡Careggi Hospital, University of Florence, Firenze, Italy, §Sacro Cuore Don Calabria Hospital - Negrar, Verona, Italy, ||ULSS 15 Alta Padovana, Camposampiero, Italy, ¶Azienda Ospedaliera Spedali Civili, Brescia, Italy, #Azienda Ospedaliera 'Ospedale Maggiore' di Crema, Crema, Italy, **Ospedale Civile di Conegliano Veneto, Vento, Italy, ††Nuovo Ospedale delle Apuane, Massa, Italy, ‡‡Policlinico Casilino, Rome, Italy, §§AO Universitaria Osp. Riuniti, Clinica di Cardiologia e Aritmologia, Torrette, Ancona, Italy, |||| Ospedale Centrale di Bolzano, Divisione di Cardiologia, Bolzano, Italy, ¶¶ University of Florence, Firenze, Italy, and ¶¶ IRCCS Multimedica, Milano, Italy.*

BACKGROUND Pulmonary vein isolation (PVI) is a cornerstone ablation strategy in the management of patients with atrial fibrillation (AF). Consensus guidelines and statements recommend PVI during the index catheter ablation procedure in patients with paroxysmal and persistent AF.

OBJECTIVE The objective of this analysis was to evaluate patients with persistent and long-standing persistent AF who were treated with the cryoballoon ablation catheter by PVI technique.

METHODS Consecutive patients with drug-refractory symptomatic persistent and long-standing persistent AF who underwent cryoballoon catheter ablation by a PVI-only procedure were prospectively included in this single-arm multicenter evaluation. Data on procedural characteristics, safety, and long-term freedom from AF recurrence were analyzed.

RESULTS Four hundred eighty-six subjects (mean age 60.8 ± 9.3 years; 389 (80%) men; 434 (89.3%) with persistent AF; 52 (10.7%) with long-standing persistent AF; left atrial diameter 44.6 ± 6.2 mm) underwent cryoballoon ablation in 35 Italian cen-

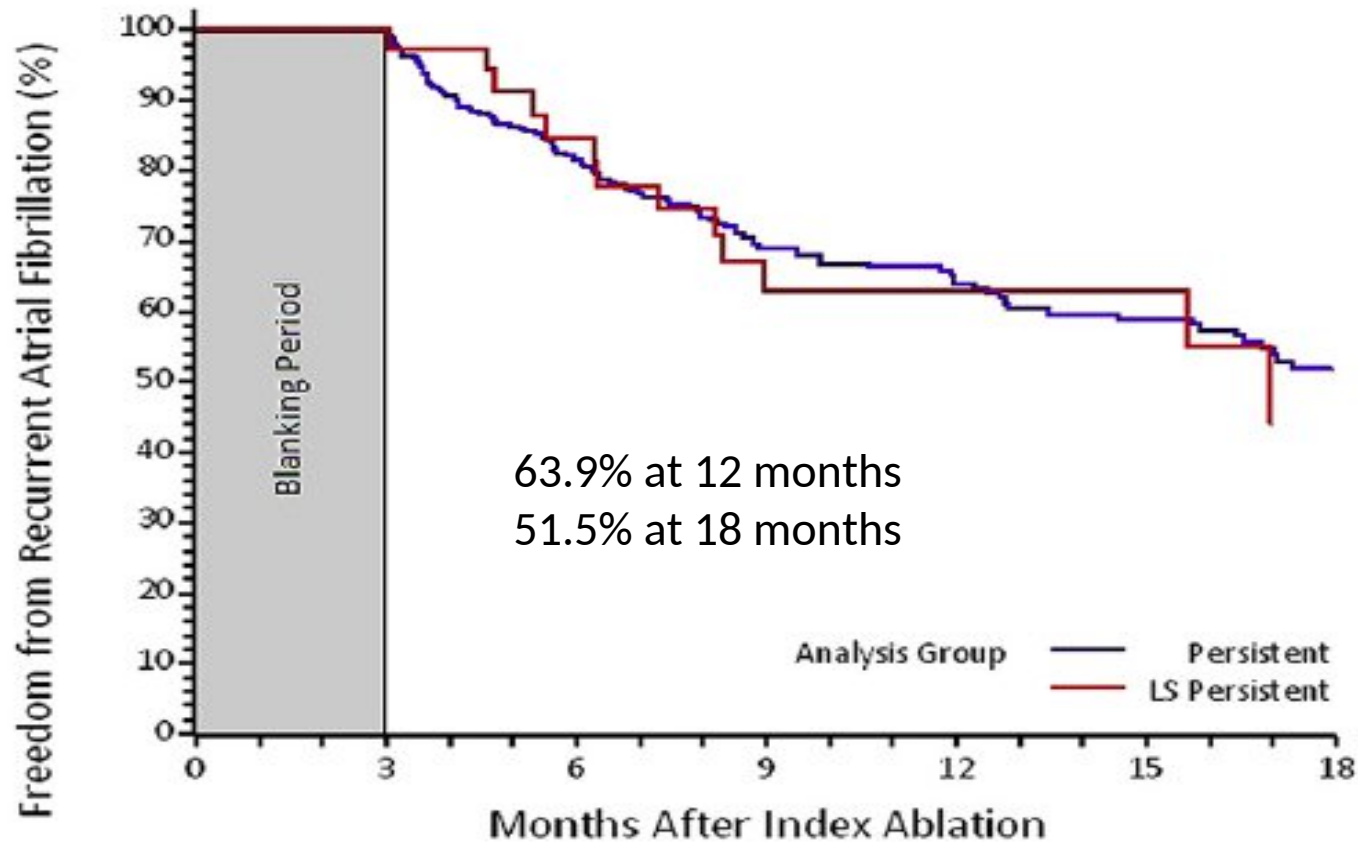
ters. The mean procedure time (skin-to-skin) was 109.9 ± 52.9 minutes, and the mean fluoroscopy time was 29.6 ± 14.5 minutes. Periprocedural complications were observed in 21 subjects (4.3%), and the acute PVI success rate was 97.6% across all patients. Using a 90-day blanking period, the single procedure Kaplan-Meier estimates of AF event-free survival were 63.9% at 12 months and 51.5% at 18 months.

CONCLUSION In this multicenter evaluation of cryoballoon ablation, the PVI procedure was safe, effective, and efficient with regard to the treatment of patients with persistent and long-standing persistent AF. The reasonable mid-term success rates agree with current clinical studies that establish PVI as a cornerstone index ablation strategy.

KEYWORDS Catheter ablation; Cryoablation; Cryoballoon; Outcomes; Persistent atrial fibrillation; Pulmonary vein isolation; Recurrence of atrial fibrillation

(Heart Rhythm 2018;15:363–368) © 2017 Heart Rhythm Society. All rights reserved.

486 consecutive pts
1STOP Project

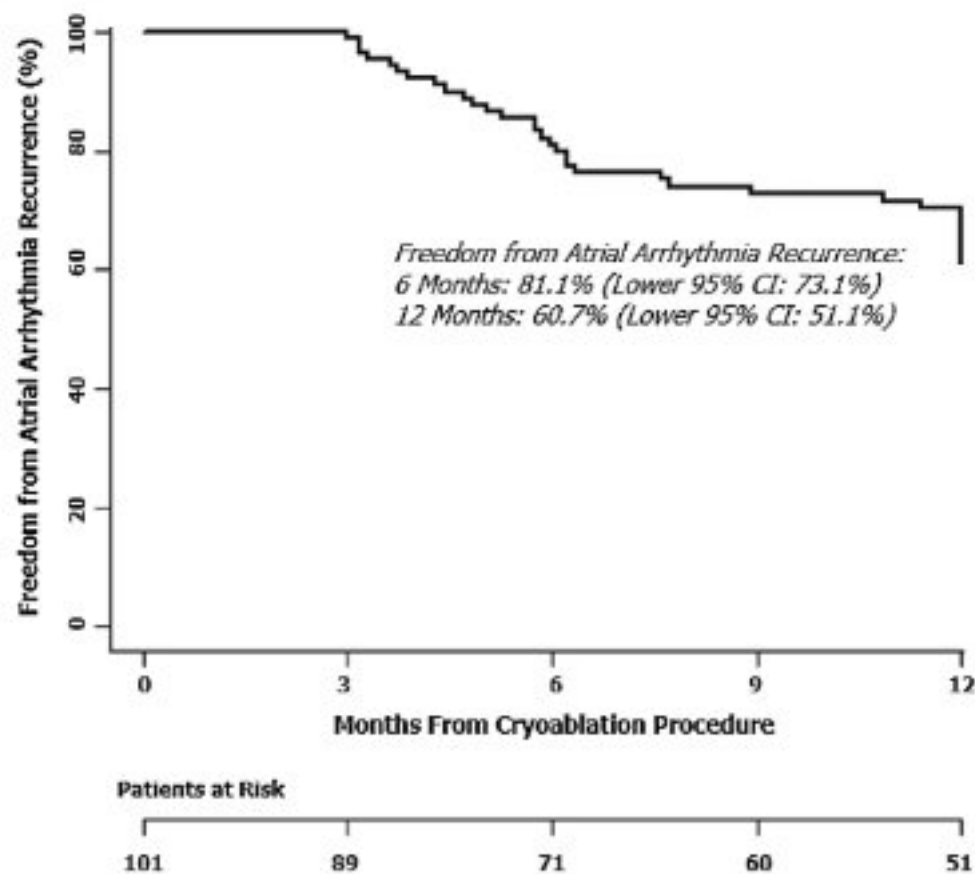


No. at Risk							
Persistent	434	317	204	136	109	80	53
LS Persistent	52	38	26	16	13	10	4

Figure 2 Kaplan-Meier estimate of freedom from atrial fibrillation recurrence in the population of patients with persistent and long-standing (LS) persistent atrial fibrillation.

Tondo C et al, Heart Rhythm 2018

FIGURE 2 Freedom From Atrial Fibrillation, Atrial Flutter, Atrial Tachycardia Recurrence



Kaplan-Meier curve of time to first atrial fibrillation, atrial flutter, or atrial tachycardia recurrence. Subjects with a primary endpoint >12 months from index cryoablation had their time to primary endpoint set to 12.0 months. CI = confidence interval.

Single-Procedure Outcomes and Quality-of-Life Improvement 12 Months Post-Cryoballoon Ablation in Persistent Atrial Fibrillation

Results From the Multicenter CRYO4PERSISTENT AF Trial

Serge Boveda, MD,^a Andreas Metzner, MD,^b Dinh Q. Nguyen, MD,^c K.R. Julian Chun, MD,^d Konrad Goehl, MD,^e Georg Noelker, MD,^f Jean-Claude Deharo, MD,^g George Andrikopoulos, MD,^h Tillman Dahme, MD,ⁱ Nicolas Lellouche, MD,^j Pascal Defaye, MD^k

JACC: CLINICAL ELECTROPHYSIOLOGY VOL. 4, NO. 11, 2018
NOVEMBER 2018:1440-7

101 pts

AF burden 100% documented by preablation Holter monitoring

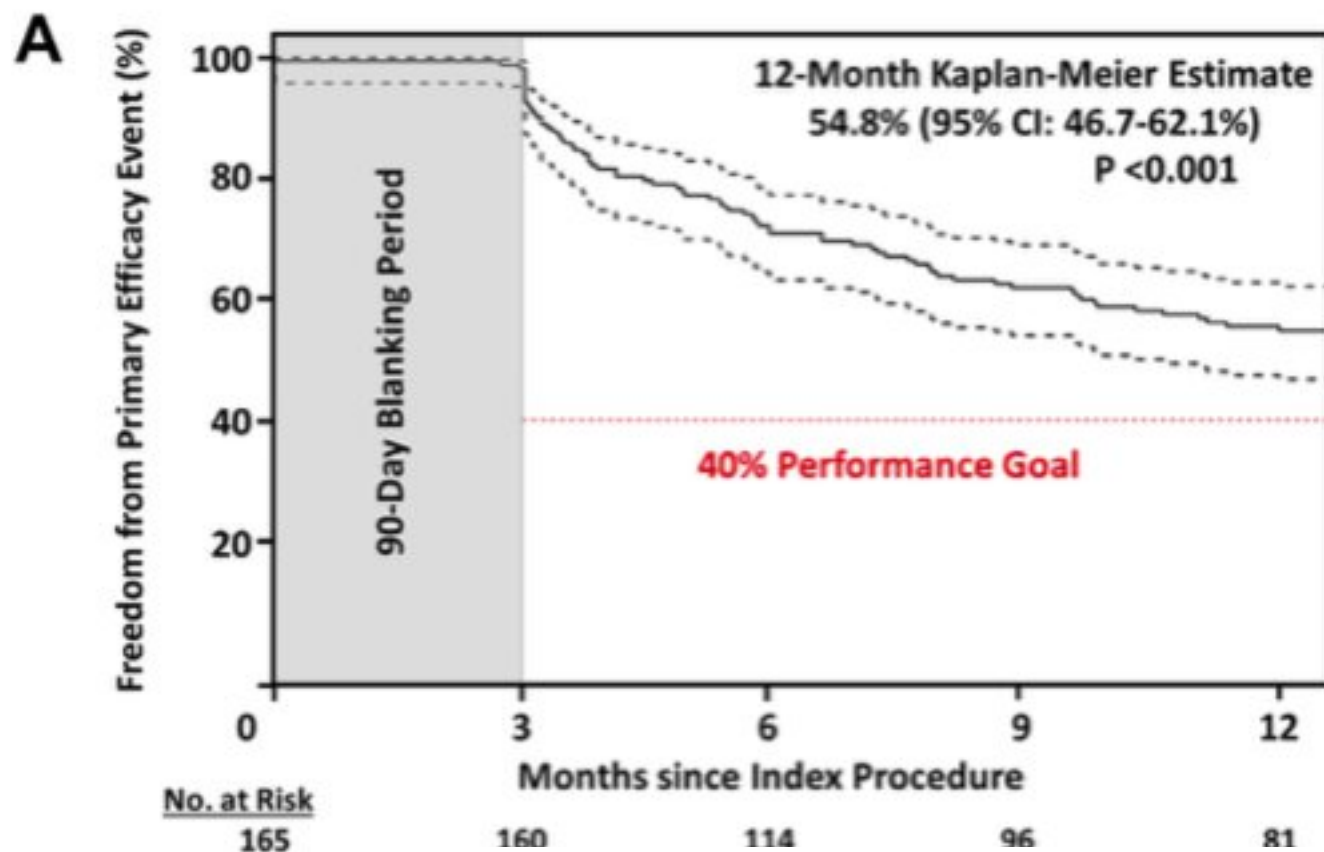
60.7% freedom from any atrial fibrillation/flutter off drugs, at 12 months

Cryoballoon ablation of pulmonary veins for persistent atrial fibrillation: Results from the multicenter STOP Persistent AF trial



Wilber W. Su, MD, FHRS,* Vivek Y. Reddy, MD,[†] Kabir Bhasin, MD,[‡] Jean Champagne, MD,[§]
 Robert M. Sangrigoli, MD,[¶] Kendra M. Braegelmann, PhD,^{||} Fred J. Kueffer, MS,^{||}
 Paul Novak, MD,** Sanjaya K. Gupta, MD, FHRS,^{††} Teiichi Yamane, MD, PhD, FHRS,^{‡‡}
 Hugh Calkins, MD, FHRS, CCDS,^{§§} on behalf of the STOP Persistent AF Investigators

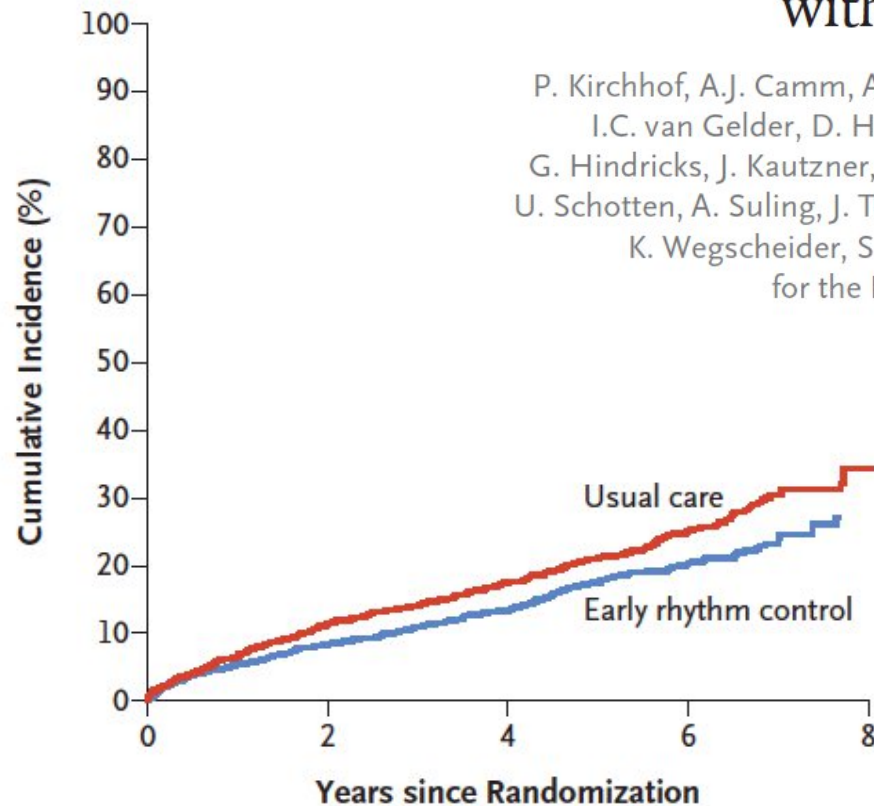
Heart Rhythm, Vol 17, No 11, November 2020



(Heart Rhythm 2020;17:1841–1847) © 2020 Heart Rhythm Society.

Early Rhythm-Control Therapy in Patients with Atrial Fibrillation

P. Kirchhof, A.J. Camm, A. Goette, A. Brandes, L. Eckardt, A. Elvan, T. Fetsch, I.C. van Gelder, D. Haase, L.M. Haegeli, F. Hamann, H. Heidbüchel, G. Hindricks, J. Kautzner, K.-H. Kuck, L. Mont, G.A. Ng, J. Rekosz, N. Schoen, U. Schotten, A. Suling, J. Taggeselle, S. Themistoclakis, E. Vettorazzi, P. Vardas, K. Wegscheider, S. Willems, H.J.G.M. Crijns, and G. Breithardt, for the EAST-AFNET 4 Trial Investigators*



No. at Risk

Usual care	1394	1169	888	405	34
Early rhythm control	1395	1193	913	404	26

Figure 2. Aalen-Johansen Cumulative-Incidence Curves for the First Primary Outcome.

The first primary outcome was a composite of death from cardiovascular causes, stroke, or hospitalization with worsening of heart failure or acute coronary syndrome.

October 1, 2020

N Engl J Med 2020; 383:1305-1316

DOI: 10.1056/NEJMoa2019422

Cryoablation or Drug Therapy for Initial Treatment of Atrial Fibrillation

Jason G. Andrade, M.D., George A. Wells, Ph.D., Marc W. Deyell, M.D., Matthew Bennett, M.D., Vidal Essebag, M.D., Ph.D., Jean Champagne, M.D., Jean-Francois Roux, M.D., Derek Yung, M.D., Allan Skanes, M.D., Yaariv Khaykin, M.D., Carlos Morillo, M.D., Umjeet Jolly, M.D., Paul Novak, M.D., Evan Lockwood, M.D., Guy Amit, M.D., Paul Angaran, M.D., John Sapp, M.D., Stephan Wardell, M.D., Sandra Lauck, Ph.D., Laurent Macle, M.D., and Atul Verma, M.D., for the EARLY-AF Investigators*

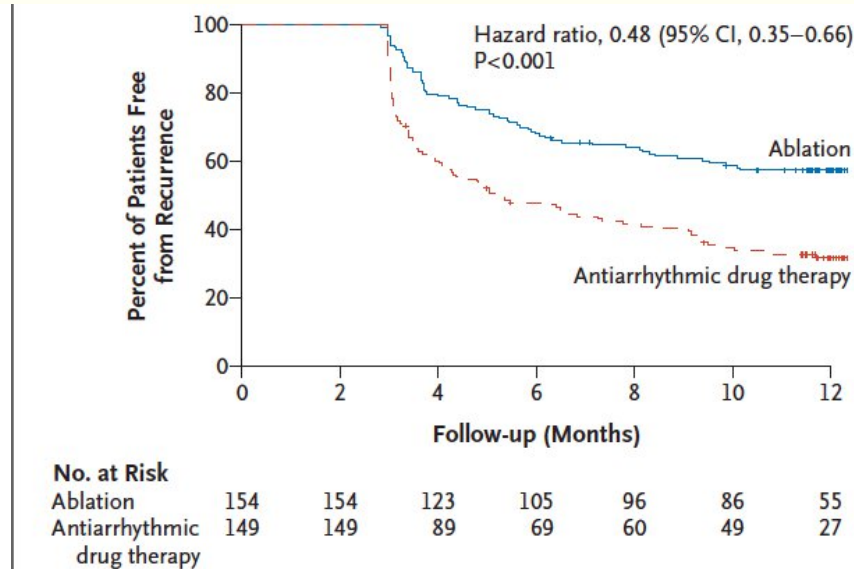


Figure 1. Freedom from Recurrence of Atrial Tachyarrhythmia over Time.

Shown are Kaplan–Meier estimates of the primary end point, freedom from recurrence of any atrial tachyarrhythmia (atrial fibrillation, atrial flutter, or atrial tachycardia) lasting 30 seconds or longer between 91 and 365 days after the initiation of an antiarrhythmic drug or catheter ablation. Tick marks indicate censored data. CI denotes confidence interval.

303 pts randomized to drug therapy or Cryoablation

All patients monitored With ILR

Cryoballoon Ablation as Initial Therapy for Atrial Fibrillation

January 28, 2021

N Engl J Med 2021; 384:316-324

DOI: 10.1056/NEJMoa2029554

Oussama M. Wazni, M.D., Gopi Dandamudi, M.D., Nitesh Sood, M.D., Robert Hoyt, M.D., Jaret Tyler, M.D., Sarfraz Durrani, M.D., Mark Niebauer, M.D., Kevin Makati, M.D., Blair Halperin, M.D., Andre Gauri, M.D., Gustavo Morales, M.D., Mingyuan Shao, Ph.D., Jeffrey Cerkvenik, M.S., Rachelle E. Kaplon, Ph.D., and Steven E. Nissen, M.D., for the STOP AF First Trial Investigators*

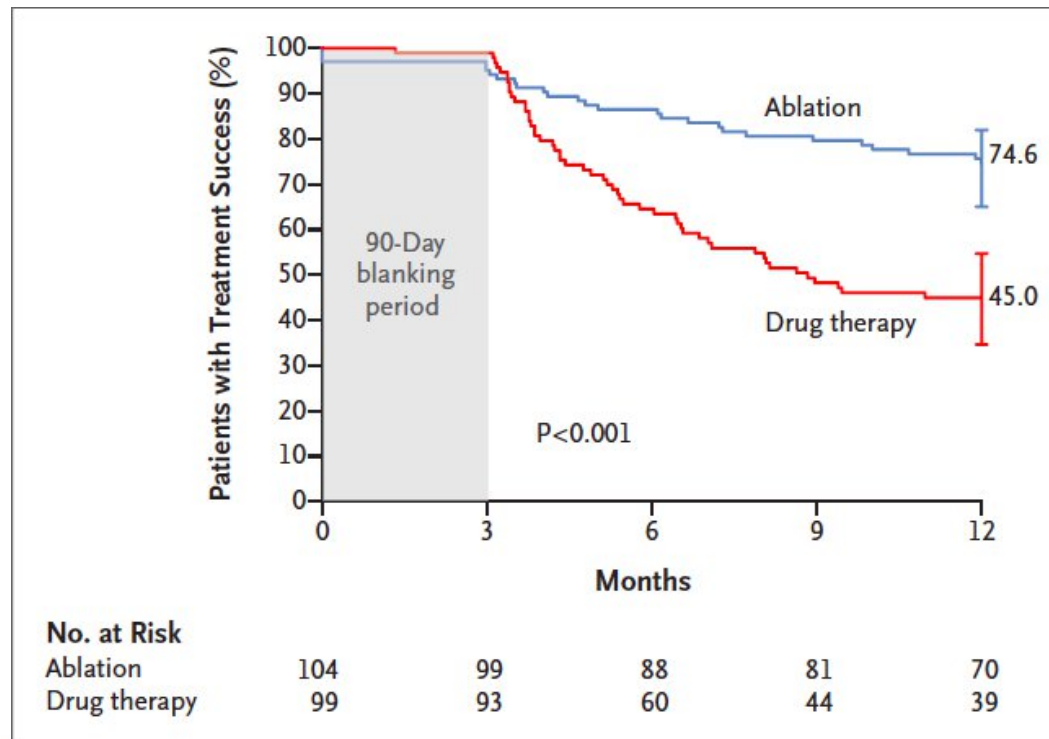
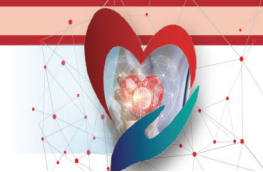


Figure 1. Treatment Success at 12 Months.



ESC

European Society
of Cardiology





Europace (2021) **23**, 1033–1041

doi:10.1093/europace/euab029

CLINICAL RESEARCH

Ablation for atrial fibrillation

Cryoballoon ablation vs. antiarrhythmic drugs: first-line therapy for patients with paroxysmal atrial fibrillation

Malte Kuniss ^{1*}, **Nikola Pavlovic** ², **Vedran Velagic**³, **Jean Sylvain Hermida**⁴, **Stewart Healey**⁵, **Giuseppe Arena**⁶, **Nicolas Badenco**⁷, **Christian Meyer** ⁸, **Jian Chen**⁹, **Saverio Iacopino**¹⁰, **Frédéric Anselme** ¹¹, **Douglas L. Packer**¹², **Heinz-Friedrich Pitschner**¹, **Carlo de Asmundis**¹³, **Stephan Willems**¹⁴, **Fabio Di Piazza**¹⁵, **Daniel Becker**¹⁶, and **Gian-Battista Chierchia**¹³; for the **Cryo-FIRST Investigators**

Cryo-FIRST: Multicenter Randomized (1:1) Controlled Trial

218

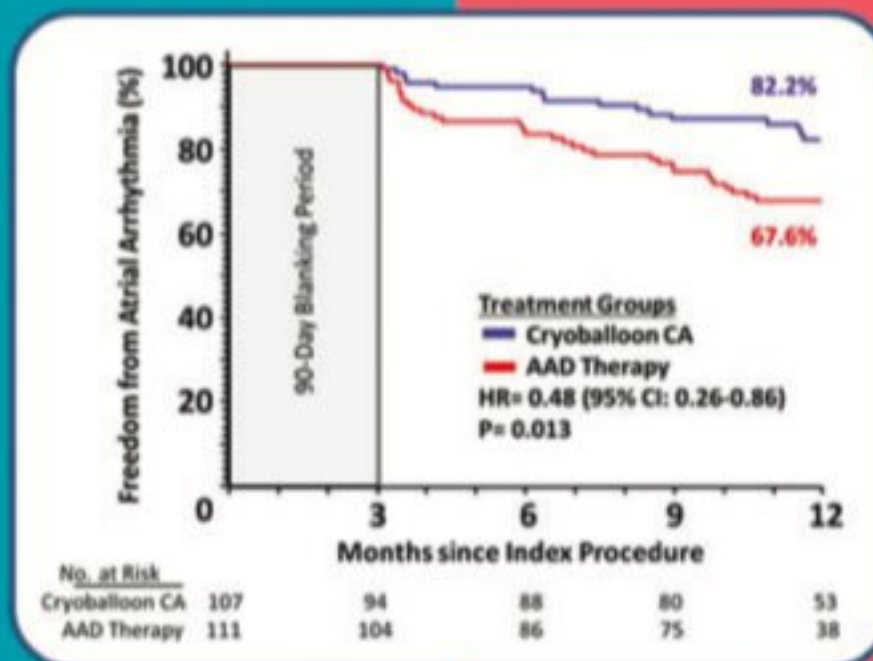
First-Line
Patients with
Symptomatic
PAF

**CRYOBALLOON CATHETER
ABLATION (CA) WITH
ARCTIC FRONT ADVANCE
N=107**



**ANTIARRHYTHMIC
DRUG (AAD) THERAPY
N=111**

82.2%



67.6%





**60% Reduction in the Incidence Rate
of Symptomatic Palpitations with
Cryoballoon CA**

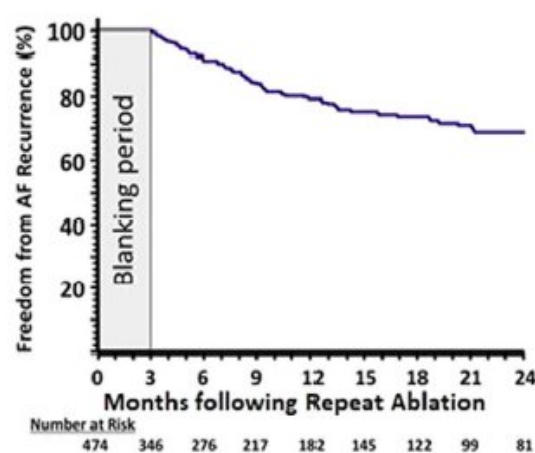
**No Difference in the Incidence Rate
of Serious Adverse Events**



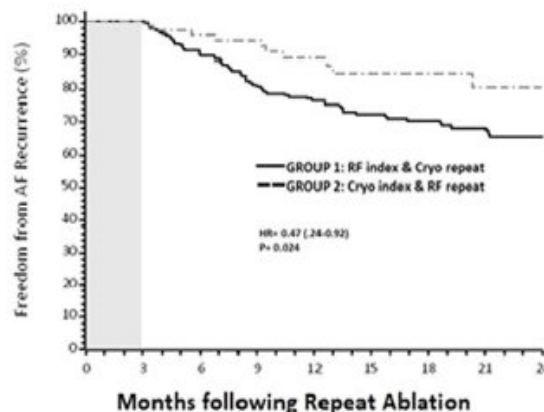
**Cryoballoon CA Results in Superior Efficacy Compared to AAD Therapy and has a
Comparable Safety Profile in Treatment Naïve Patients with
Symptomatic Paroxysmal AF**

Cryoballoon or radiofrequency ablation? Alternating technique for repeat procedures in patients with atrial fibrillation

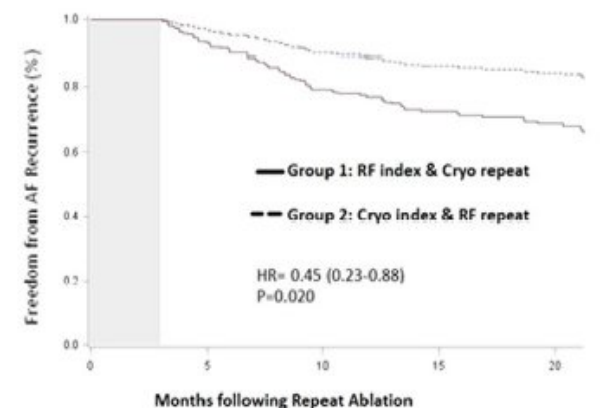
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(A)



(B)



(C)

FIGURE 3 Freedom from recurrent atrial fibrillation (AF) following the repeat catheter ablation and using a 90-day blanking period. Panel A is the total cohort, panel B is the cohort according to the groups, and panel C is adjusted for age, gender, and persistent AF history. Panel A, Unadjusted Kaplan-Meier estimate for recurrent AF in the total cohort. Panel B, Unadjusted Kaplan-Meier estimate for recurrent AF in the study according to repeat ablation cohort. Panel C, Kaplan-Meier estimate for recurrent AF for the study cohort after adjustments for age, gender, and persistent AF history [Color figure can be viewed at wileyonlinelibrary.com]



Cryoballoon Ablation for the Treatment of Atrial Fibrillation in Patients With Concomitant Heart Failure and Either Reduced or Preserved Left Ventricular Ejection Fraction: Results From the Cryo AF Global Registry

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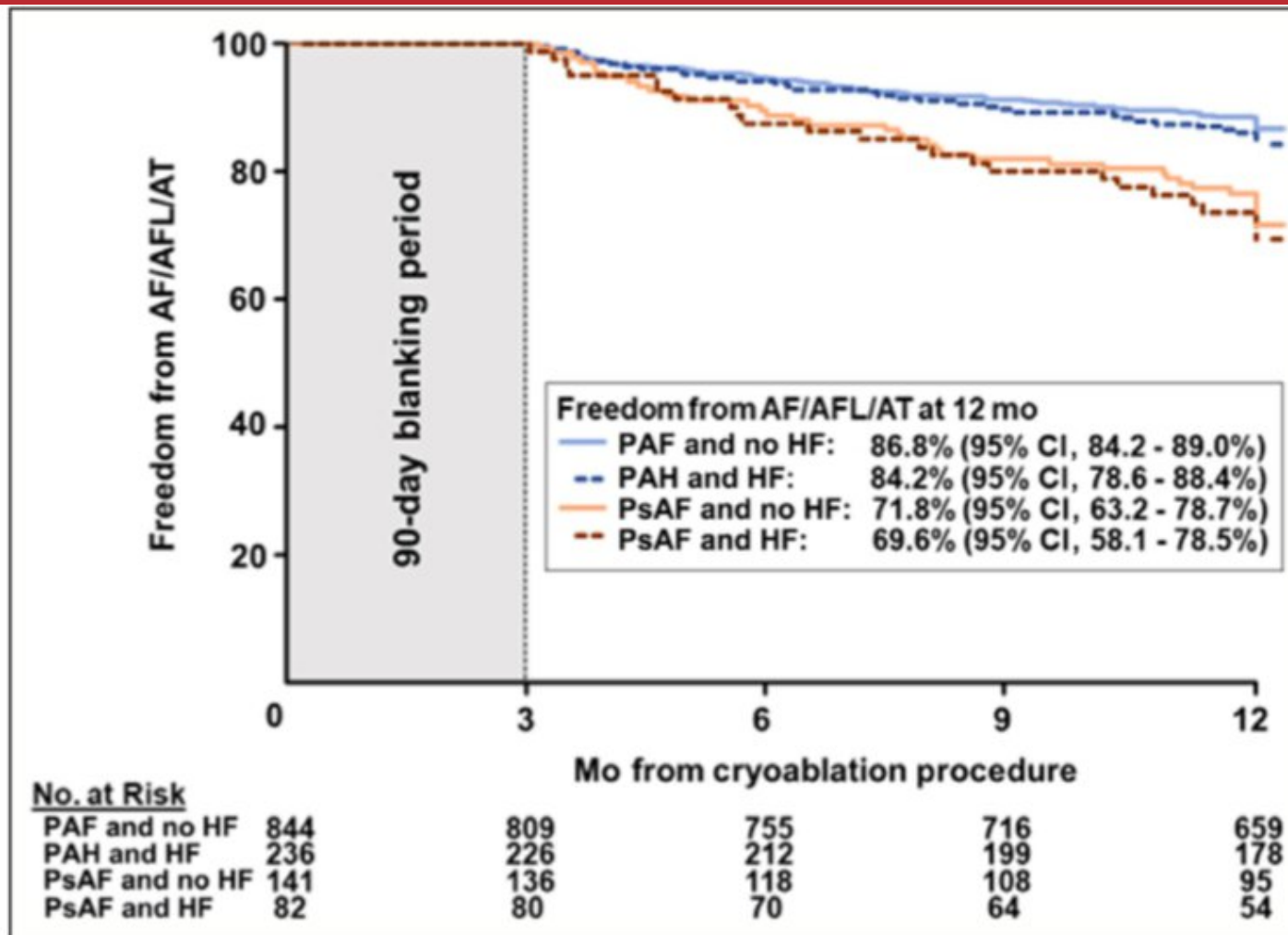


Figure 2. Freedom from atrial arrhythmia recurrence over 12 months.

Kaplan-Meier estimate of 12-month freedom from a ≥ 30 -second recurrence of atrial fibrillation (AF)/atrial flutter (AFL)/atrial tachycardia (AT) in patients with paroxysmal AF (blue) and persistent AF (red) with (dashed line) and without (solid line) heart failure (HF). Persistent AF at baseline predicted atrial arrhythmia recurrence ($P < 0.001$), but HF status did not predict arrhythmia recurrence over the 12-month follow-up ($P = 0.319$). PAF indicates paroxysmal atrial fibrillation; and PsAF, persistent atrial fibrillation.

CONCLUSIONS: CRYO ABLATION, STATE OF THE ART

- Pulmonary veins antral isolation by means of CB-2/4 is safe, highly effective and efficient
- CB ablation is at least as effective as contact-force open-irrigated RF ablation in paroxysmal AF pts, with shorter procedural time, fewer repeat ablation, less total and CV hospitalizations, less cardioversions
- CB ablation is as effective and safe in paroxysmal and, at less extension, persistent and long-lasting persistent atrial fibrillation pts
- Repeat RF ablations may have better outcome when index procedure is CB ablation
- CB ablation is highly superior to AA drug therapy as first-line therapy
- CB ablation is effective for treatment of heart failure patients with either reduced or preserved ventricular function and paroxysmal or persistent AF

Thankyou for the attention

