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SPECIAL EDITION
FOOD & ARRHYTHMIAS

Balloons, lasers, contact force sensing: will new technologies improve results of AF ?

Claudio Tondo, MD, PhD

Cardiac Arrhythmia Research Centre

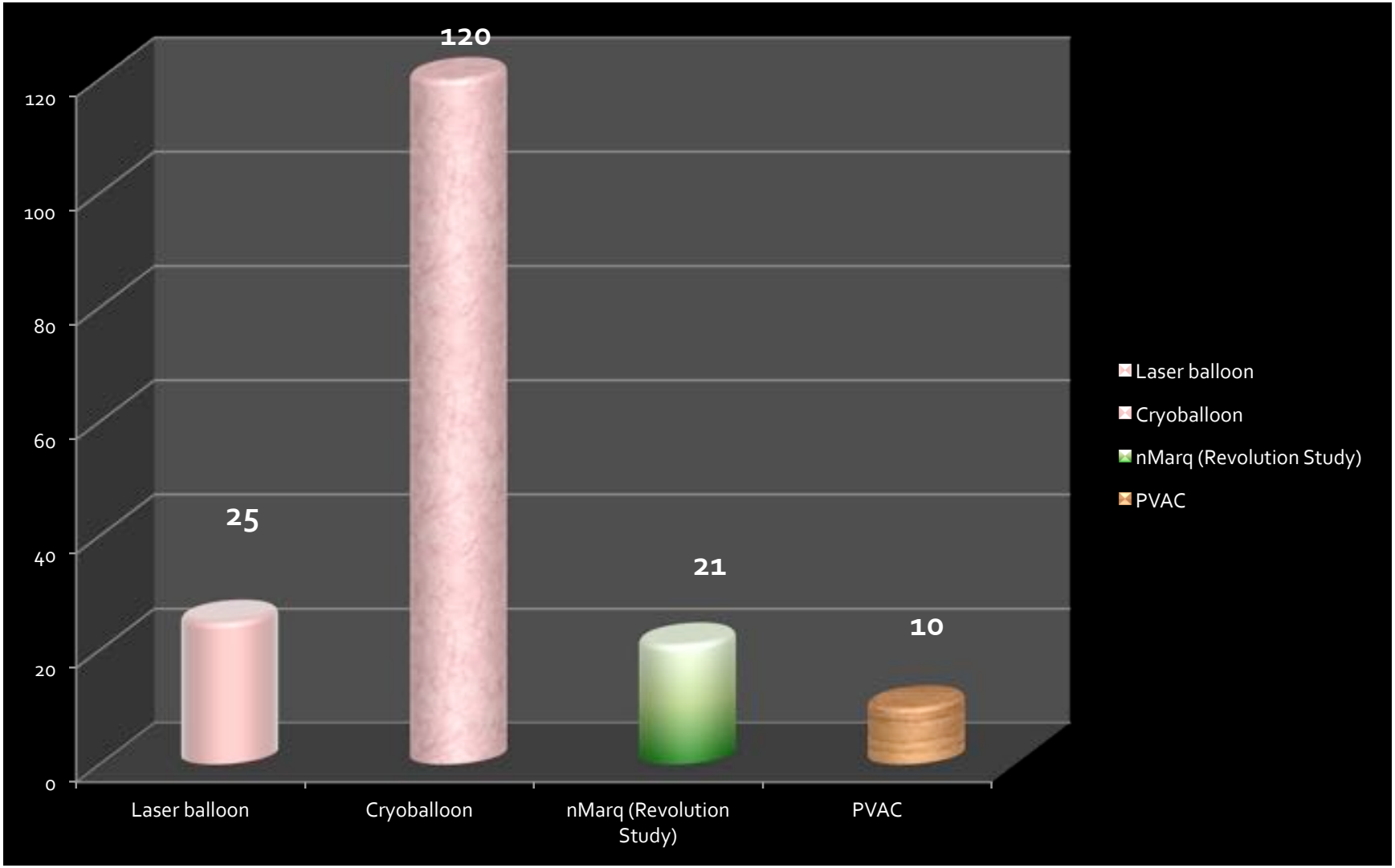
Centro Cardiologico Monzino, IRCCS

Dept. of Cardiovascular Sciences-University of Milan, Milan, Italy

and

Texas Cardiac Institute, Austin,Tx, USA

NEW TECHNOLOGIES UPDATE: CUMULATIVE CCM EXPERIENCE



Technology Advancement for Atrial Fibrillation Ablation

AGENDA

- Balloon-based technology :

1 . Cryo energy

2. Laser energy

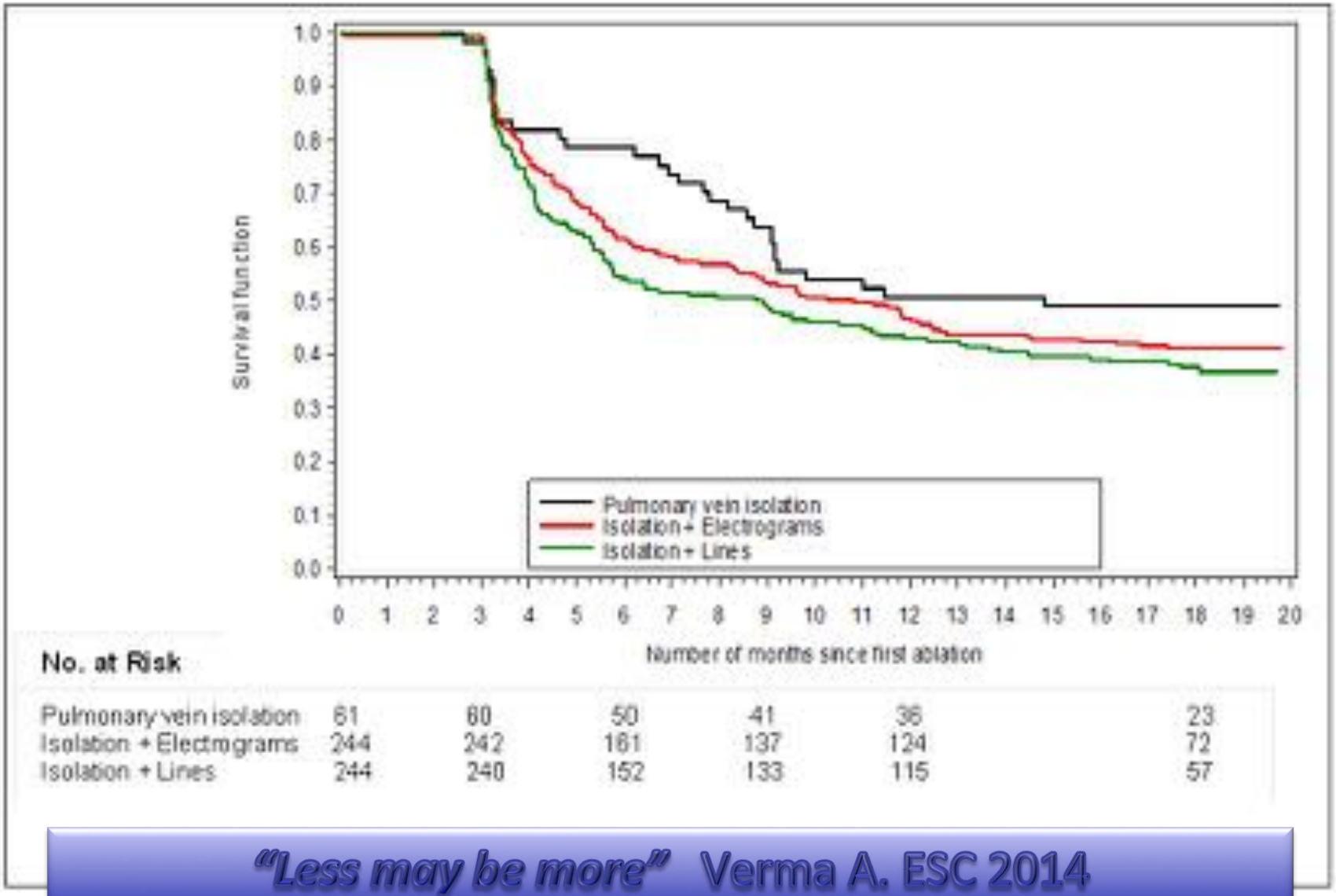
- Loop-shaped mapping catheters:

1. N-Marq
2. PVAC Gold

- RF current delivery through CF sensor technology

(ECI= Electrical Coupling Interval)

STAR AF 2 Trial



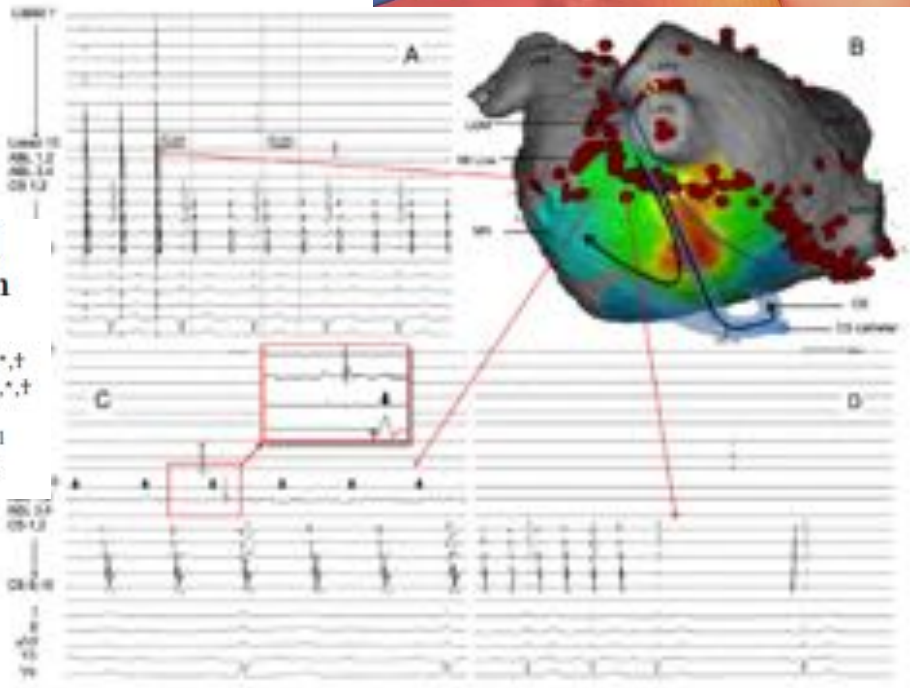
"Less may be more" Verma A. ESC 2014

Challenges Associated with the Conventional Focal Ablation Approach

Atrial Tachycardias Utilizing the Ligament of Marshall Region Following Single Ring Pulmonary Vein Isolation for Atrial Fibrillation

WILLIAM W.B. CHIK, M.B.B.S.,*,† JACKY KIT CHAN, M.B.B.S.,*,‡ DAVID L. ROSS, PH.D.,*,† JACKIE WAGSTAFF, R.N.,* EDDY KIZANA, PH.D.,*,† ARAVINDA THIAGALINGAM, PH.D.,*,† PRAMESH KOVOOR, PH.D.,*,† and STUART P. THOMAS, PH.D.*,†

From the *Cardiology Department, Westmead Public and Private Hospitals, Sydney, Australia; †Sydney Medical School, University of Sydney, Sydney, Australia; and ‡Ruttonjee and Tang Shiu Kin Hospitals, Wan Chai, Hong Kong, SAR



EDITORIAL COMMENTARY

Simplifying atrial fibrillation ablation: How far can we go?

German GAP-AF (AFNET 1) prospective randomized multicenter trial

• At three month follow-up, sinus rhythm had been achieved in 37.8% (46) of patients who had complete ablation, versus 20.8% (26) with incomplete ablation (P<0.001).

• Mean number of days in sinus rhythm was 60 days for the complete group versus 16 days for the incomplete group (P<0.001).

• At three months, when patients were taken back to the EP lab for a repeat investigation, 70 % of those randomized to complete PVI had gaps versus 89% randomized to incomplete PVI.

"The study shows us for the first time that complete isolation of the pulmonary veins is more effective than incomplete isolation".

KH Kuck.

EHRA EUROPACE 2013

New technologies for AF

FTI

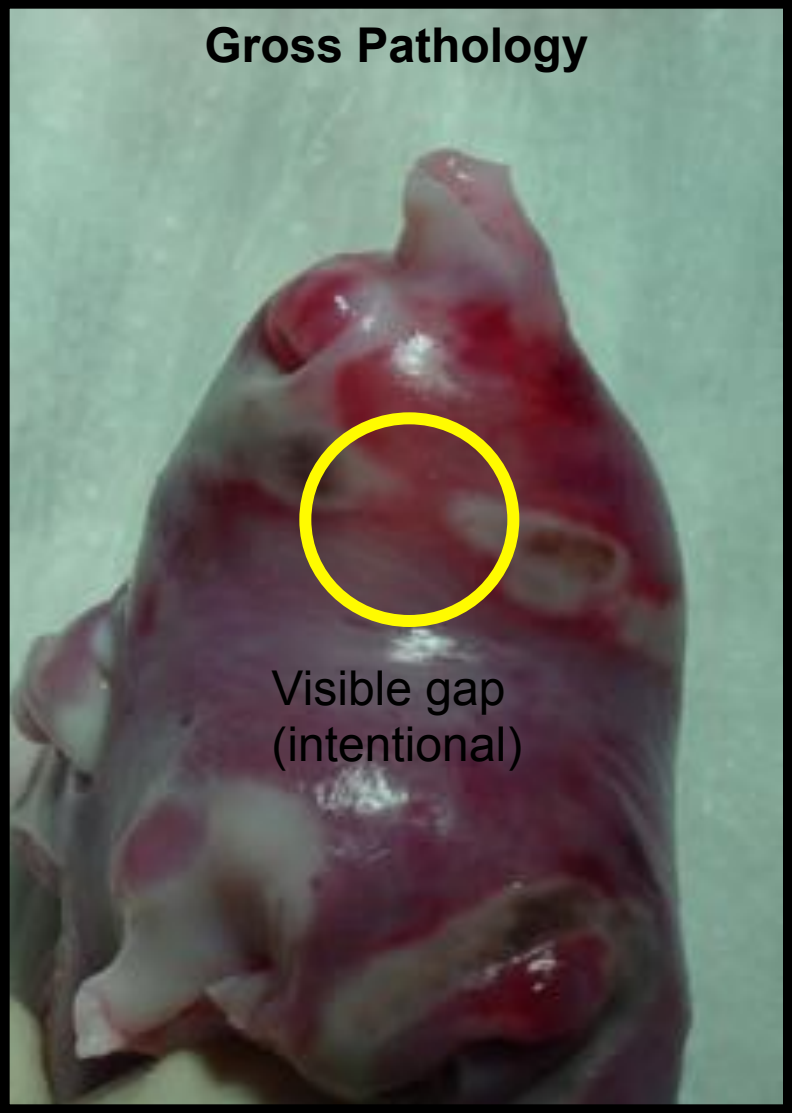
Force Time Integral

LSI

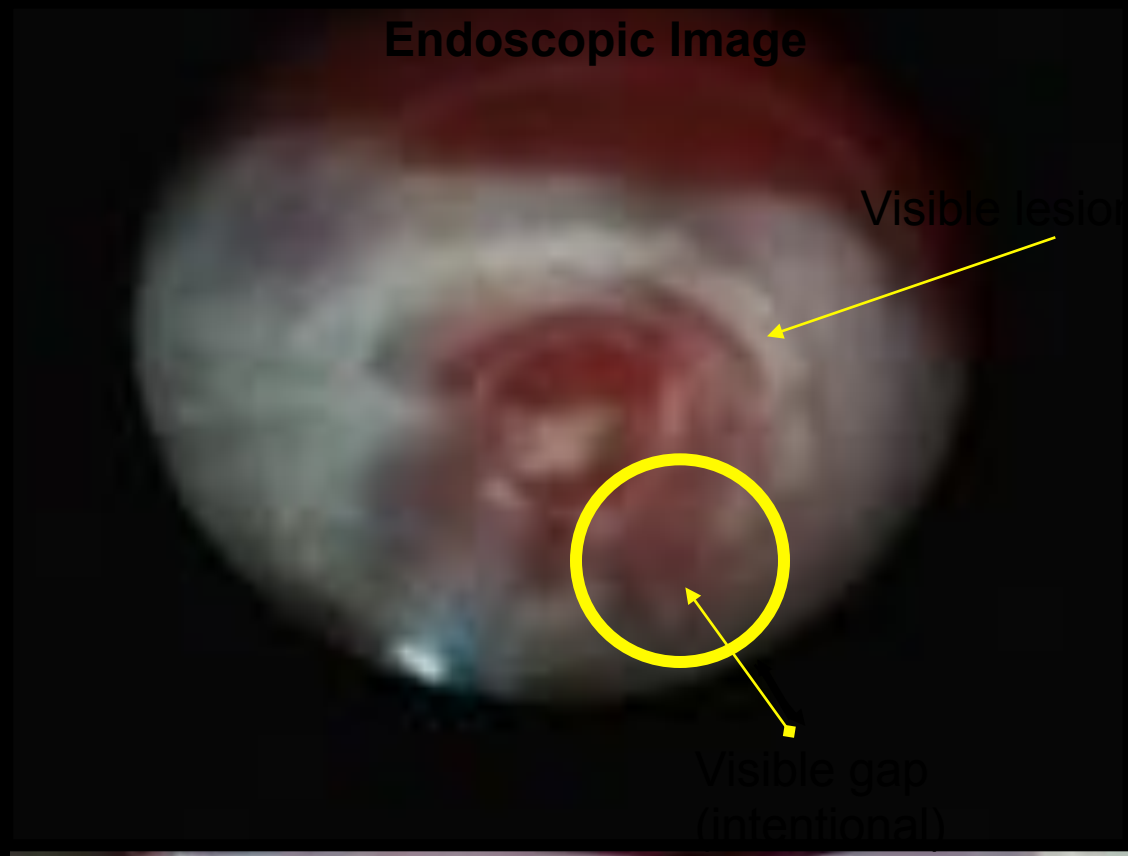
Lesion Index

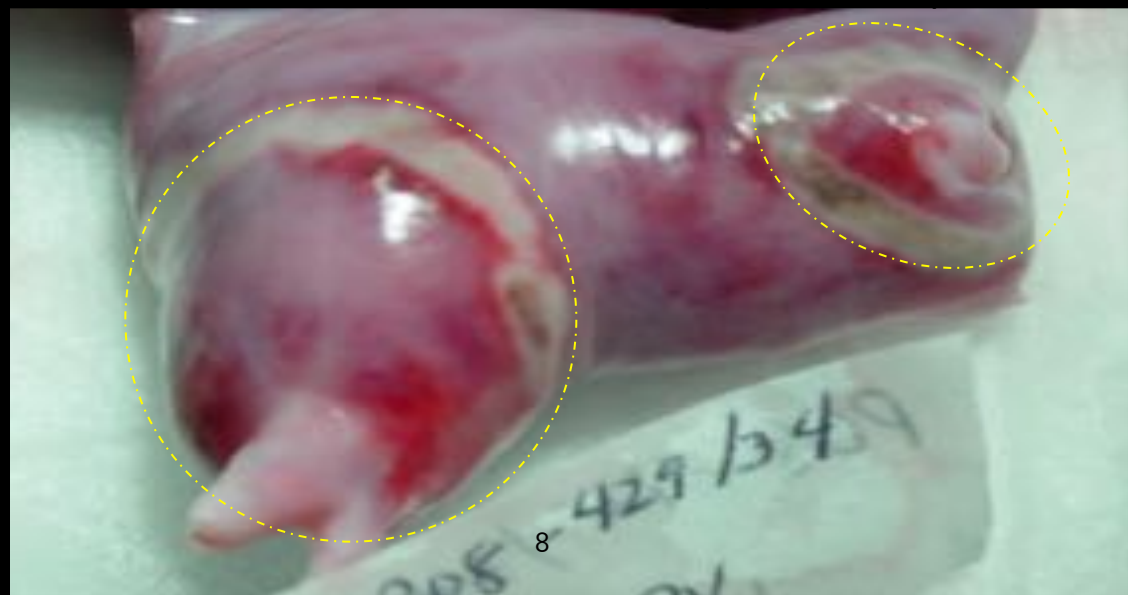
The only index assessing real-time lesion size combining information from Force, Time and Power

Gross Pathology



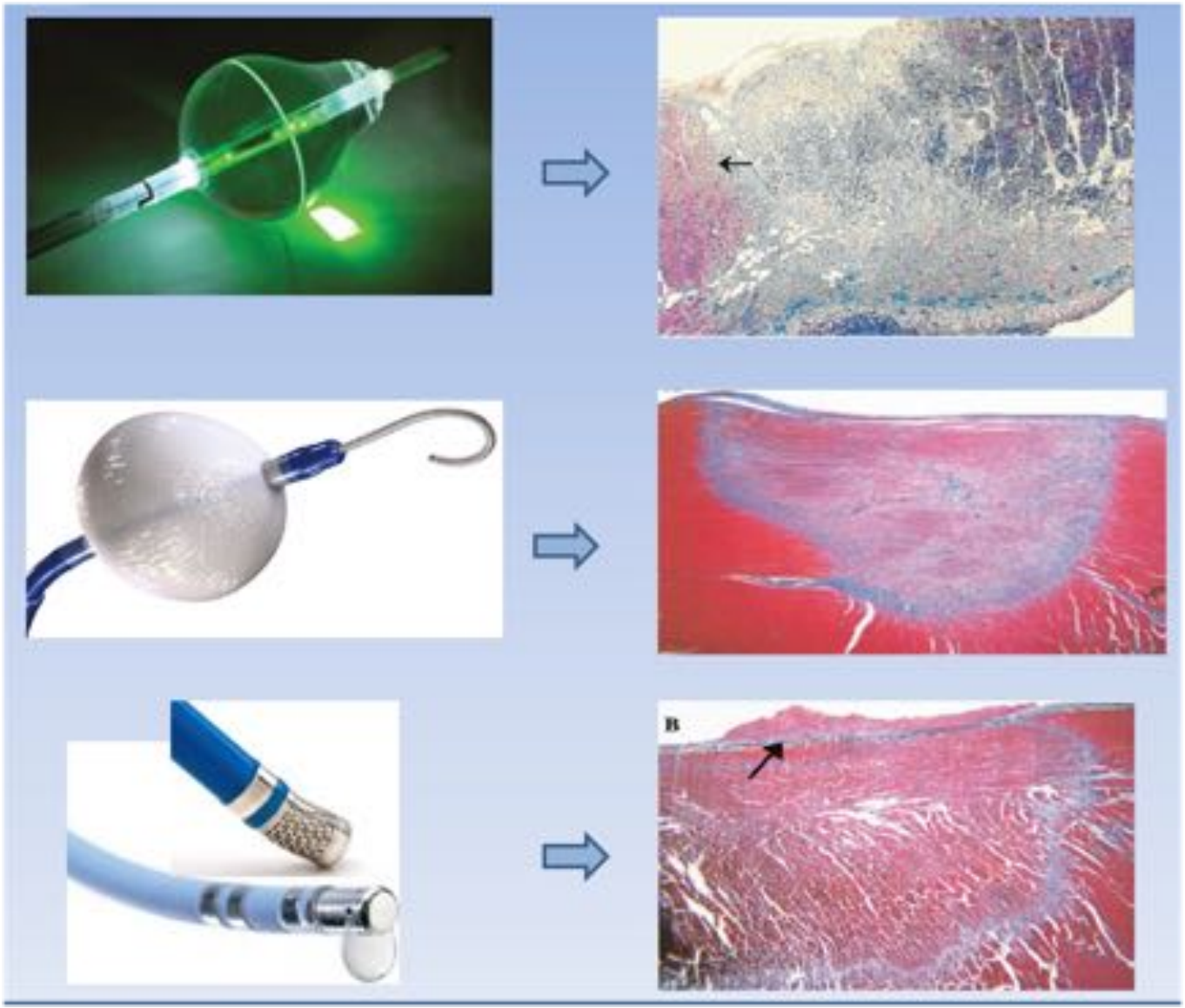
Endoscopic Image





CardioFocus U. Miami Pig P08-429/34
EAS-AC Ablation August 11, 2008
Vivek Reddy, MD

Different type of lesion



2012

Europace
doi:10.1093/europace/eus027

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

"…point-by-point RF energy and Cryoballoon ablation are the two standard ablation systems used for catheter ablation of AF today…"

authors have reported they have no relationships relevant to the contents of this paper to disclose.

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

the last ablation attempt (including redos within the blanking period), respectively, in the cohorts fo
(blue lines). **Thin vertical lines** = mean follow-up times for the 2 groups.

Birgit Wellmann, Cordula Kreft, and Simone Kolish
with data management and follow-up, Astrid Kleemey

The first repeat procedures, whether cryoballoon or radiofrequency ablation, increased the percentage of recurrence-free patients by 13.3 percentage points. Subsequent repeat procedures increased rates by a fraction of this amount. Two conclusions might be drawn. First, cryoablation is an equally valid alternative to radiofrequency for repeat procedures. Second, lack of success is most likely due to underlying pathologies rather than to the method used. If so, the challenge would be to identify in advance this subgroup of patients who are particularly resistant to PVI and consider alternative treatments, rather than attempt incremental procedural improvements.

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Long-term rates of freedom from AF over several years after cryoballoon ablation appear comparable to those with radiofrequency energy ablation.

sulting, Wayland, Massachusetts; and the ‡‡Massachusetts General Hospital, Boston, Massachusetts. The STOP AF study was funded by Medtronic, Inc. (which purchased Cryocath over the course of the study). Dr. Packer receives research funding from Biosense Webster, Boston Scientific/EPT, Endosense, EpiEP, EP Advocate, Medtronic CryoCath LP, Minnesota Partnership for Biotechnology and Medical Genomics/University of Minnesota, National Institutes of Health, St. Jude

Dr. Whee
Dr. Irwin
Guerra is
service on
a research
service on

in 17 cases, a 28-mm balloon in 9 cases, with both sizes no
in 2 cases, and with only the Freezor M
one reablation case.

Stroke occurrence/neurologic events. Str
5 of 228 (2.2%) randomized and crosso
patients. One procedure-related stroke occu
of intervention in a patient crossing ove
cryoablation therapy, which was the only pr
stroke event (0.4%, 1 of 228). An additi
sustained nonprocedure-related cerebral vas
follow-up. In 1 postablation patient, a sm
stroke occurred on day 183 of follow-up,
ablation for atrial flutter. A second patient
lacunar infarct of indeterminate age on CT
day 51. An additional patient had transien

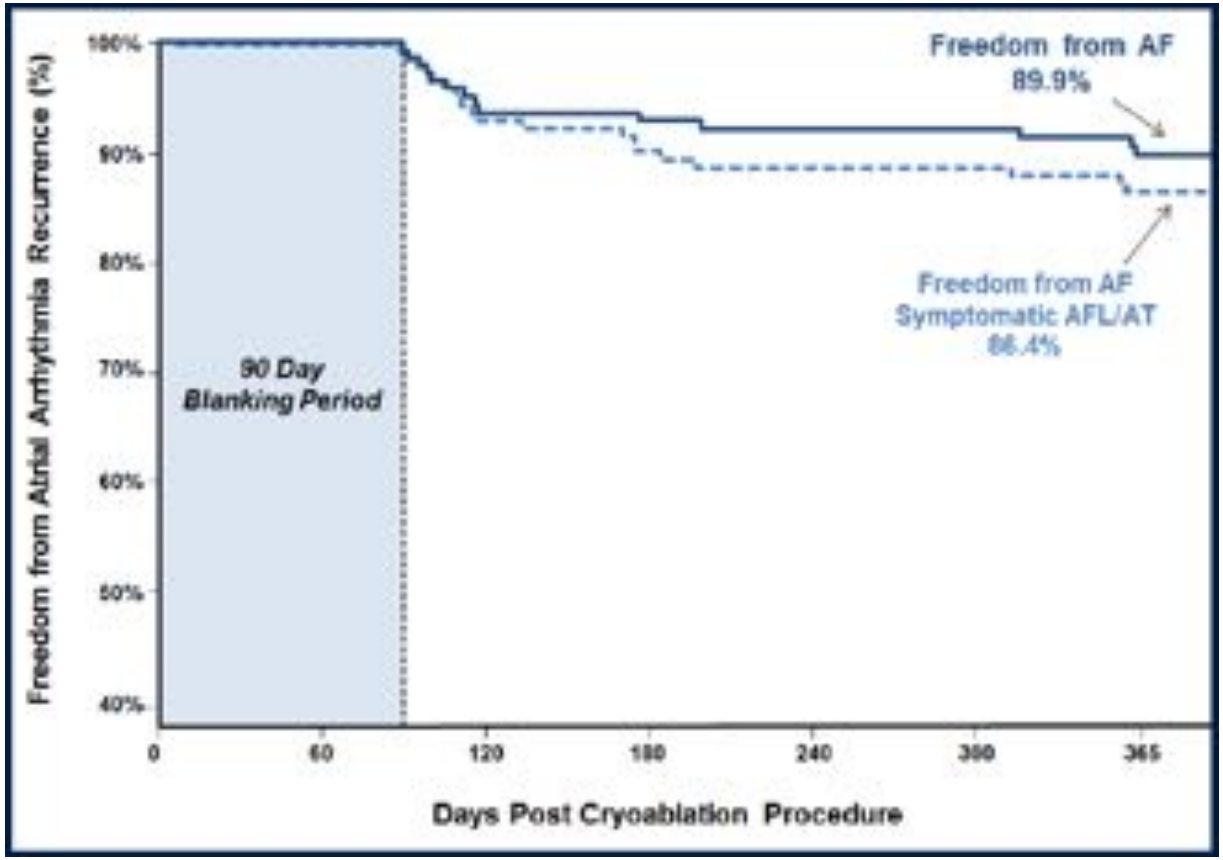
Stroke	0	0.0	4
TIA	0	0.0	3
Tamponade	0	0.0	1
Myocardial infarction	0	0.0	2
Hemorrhage requiring transfusion	1	1.2	3
New atrial flutter	12	14.6	6
Atrial esophageal fistula	0	0.0	0
Death	0	0.0	1
New or worsened arteriovenous fistula	0	0.0	2
Pseudoaneurysm	0	0.0	1
Phrenic nerve palsy	0	0.0	22
Persistent phrenic nerve palsy	0	0.0	4
PV stenosis	0	0.0	5

PV = pulmonary vein; TIA = transient ischemic attack.

The STOP AF trial demonstrates that cryoballoon ablation is effective in preventing recurrent, symptomatic, paroxysmal AF in patients who are resistant to at least one antiarrhythmic drug.

STOP AF: second generation CB interim results HRS 2015

- Nearly 90% freedom from AF at 12 months (n=146)
- 12 month freedom for AF and symptomatic AFL/AT was 86.4% (n=146)
- Low 2.9% (10/341) repeat ablation rate during the 90 day blanking period
- 5.9% (20/146) adverse event rate



Europace
doi:10.1093/europace/euv060

CLINICAL RESEARCH

Comparison between radiofrequency with contact force-sensing and second-generation cryoballoon for paroxysmal atrial fibrillation catheter ablation: a multicentre European evaluation

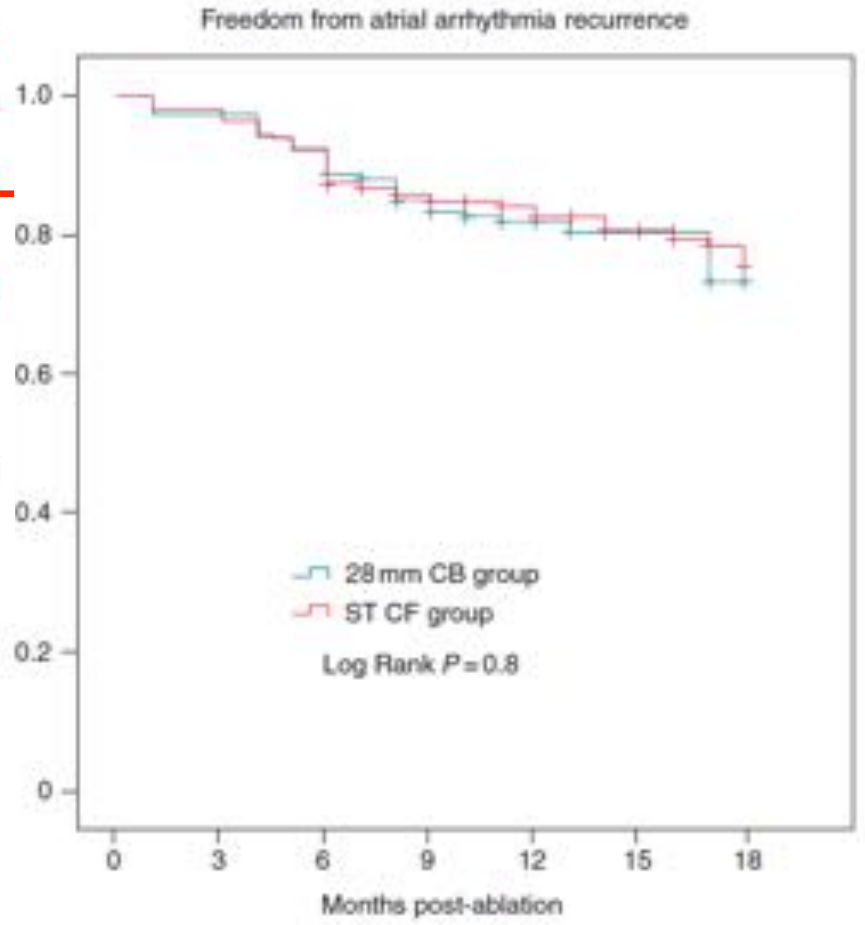
Fabien Squara[1,2*], Alexandre Zhao[2], Eloi Marijon[3,4], Decebal Gabriel Latcu[5], Rui Providencia[3], Giacomo Di Giovanni[6], Gaël Jauvert[2], Francois Jourda[3], Gian-Battista Chierchia[6], Carlo De Asmundis[6], Giuseppe Ciconte[6], Christine Alonso[2], Caroline Grimard[2], Serge Boveda[3], Bruno Cauchemez[2], Nadir Saoudi[5], Pedro Brugada[6], Jean-Paul Albenque[3], and Olivier Thomas[2]

376 patients enrolled in 4 centers: 198 in CFS group and 178 in the Cryoballoon group

Procedure time was 122.5±40.7 min for CFS compared to 109.6+40 min for Cryoballoon (p=0.003)

Overall complication rates were similar in the CFS and Cryoballoon group 7.1% vs. 7.3%, respectively

Freedom from arrhythmia recurrence was 73.3% in the Cryoballoon group compared to 76% in the CFS group (p=0.63)

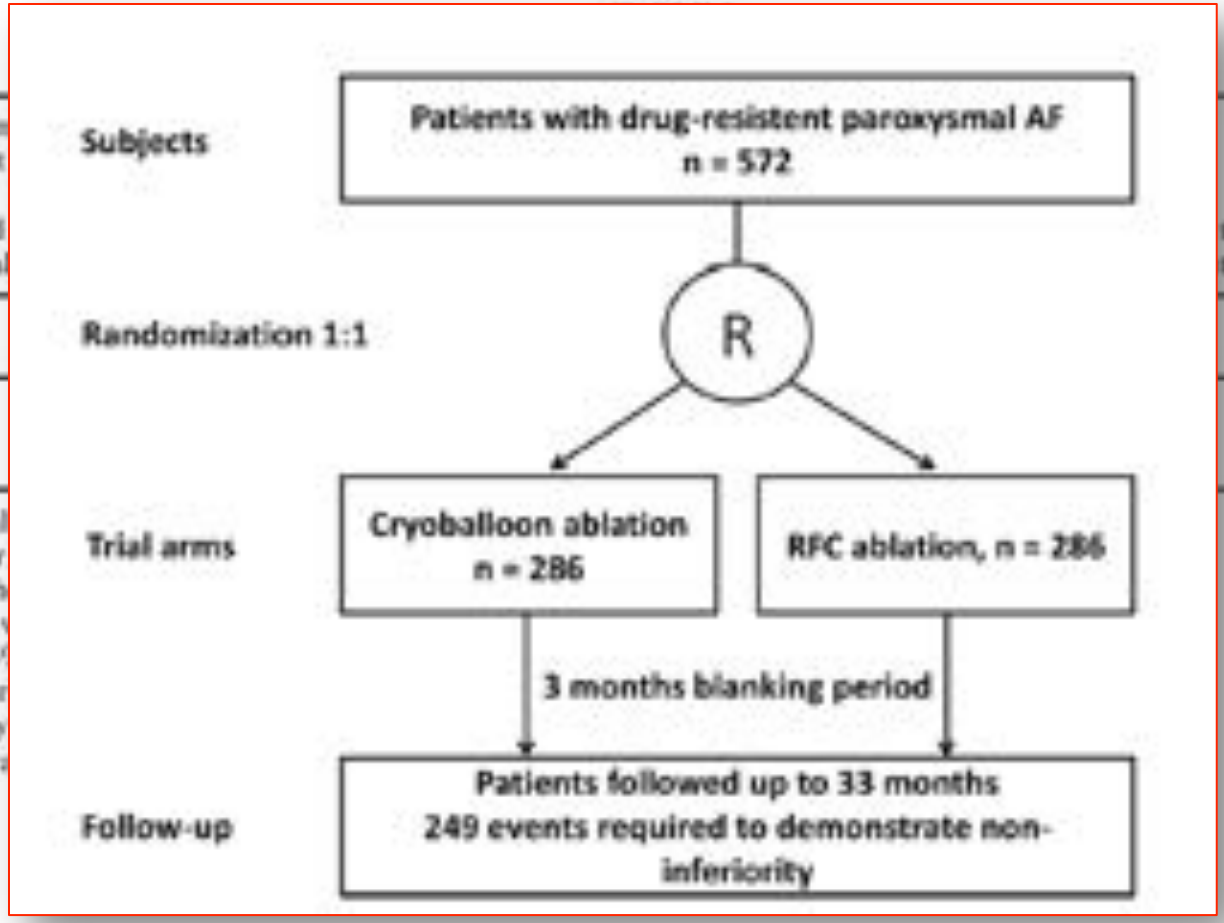


	Proportion of patients free from arrhythmia recurrence					
	3 months	6 months	9 months	12 months	15 months	18 months
ST CF group	96.2%	87.4%	84.8%	82.5%	80.4%	75.5%
28 mm CB group	97.3%	88.7%	83.4%	81.9%	80.3%	73%
	Number of patients at risk					
ST CF group	153	139	127	105	72	57
28 mm CB group	146	133	111	108	42	27

Rationale and Design of FIRE AND ICE: A Multicenter Randomized Trial Comparing Efficacy and Safety of Pulmonary Vein Isolation Using a Cryoballoon versus Radiofrequency Ablation with 3D-Reconstruction

ALEXANDER FÜRNKRANZ, M.D.,* JOSEP BRUGADA, M.D.,† JEAN-PAUL ALBENQUE, M.D., PH.D.,‡ CLAUDIO TONDO, M.D., PH.D.,§ KURT BESTEHORN, M.D., PH.D.,¶ KARL WEGSCHEIDER, PH.D.,** FEIFAN OUYANG, M.D.,†† and KARL-HEINZ KUCK, M.D.††

From the *Cardioangiologisches Centrum Bethanien, Wilhelm Epstein Strasse, Frankfurt, Germany; †Hospital Clinic, University of Barcelona, Villarroel, Barcelona, Spain; ‡Clinique Pasteur, Toulouse Cedex 3, France; §Department of Cardiovascular Medicine, Cardiac Arrythmia Research Centre, Centro Cardiologico Monzino, University of Milan, Milan, Italy; ¶IKKF GmbH, Munich, Germany; **Institut für Medizinische Biometrie und Epidemiologie, Universitätskliniken Hamburg-Eppendorf, Hamburg, Germany, and ††Asklepios Klinik

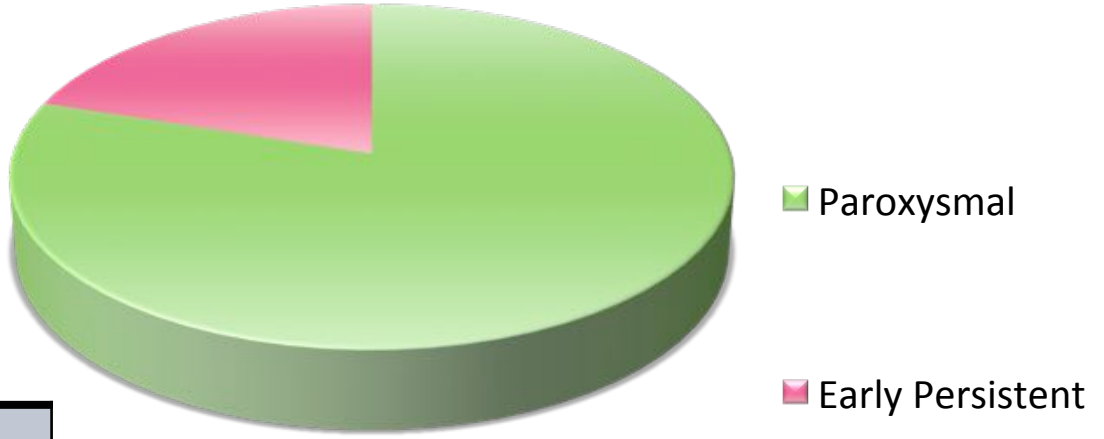


Cardiac Arrhythmia Research Center-Centro Cardiologico

Cryoballoon: Single Center experience

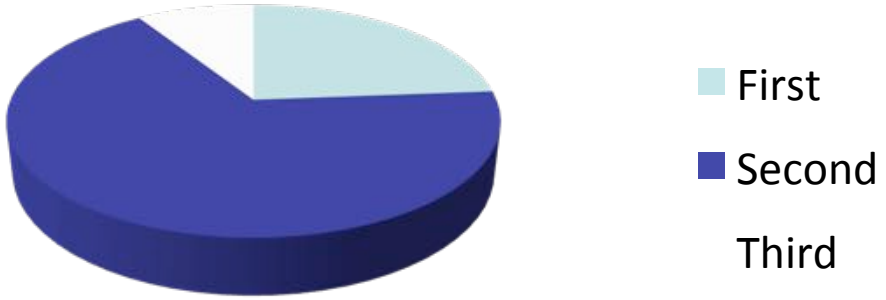
328 patients treated

240 pts with 1 at least 1y follow up



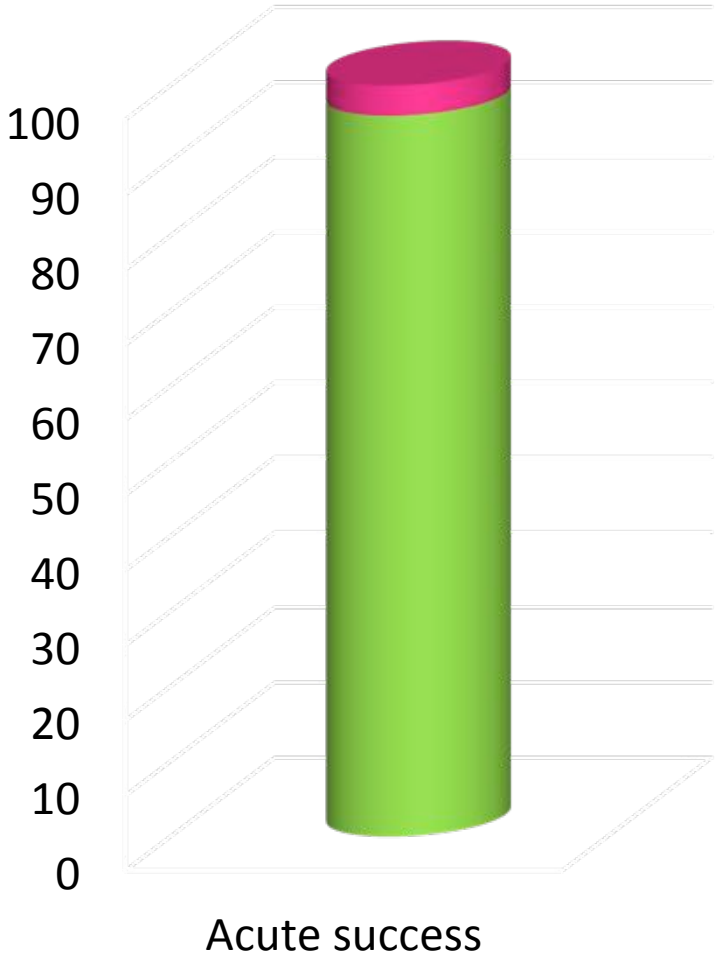
CAD	10 %
Hypertension	21 %
Valve disease	6.3 %
LA area (mean±SD)	20.9±4.9
LVEF (mean±SD)	65±4.3
AADs failure	90 %
AADs / pts	1.6

CB generation



Cardiac Arrhythmia Research Center-Centro Cardiologico

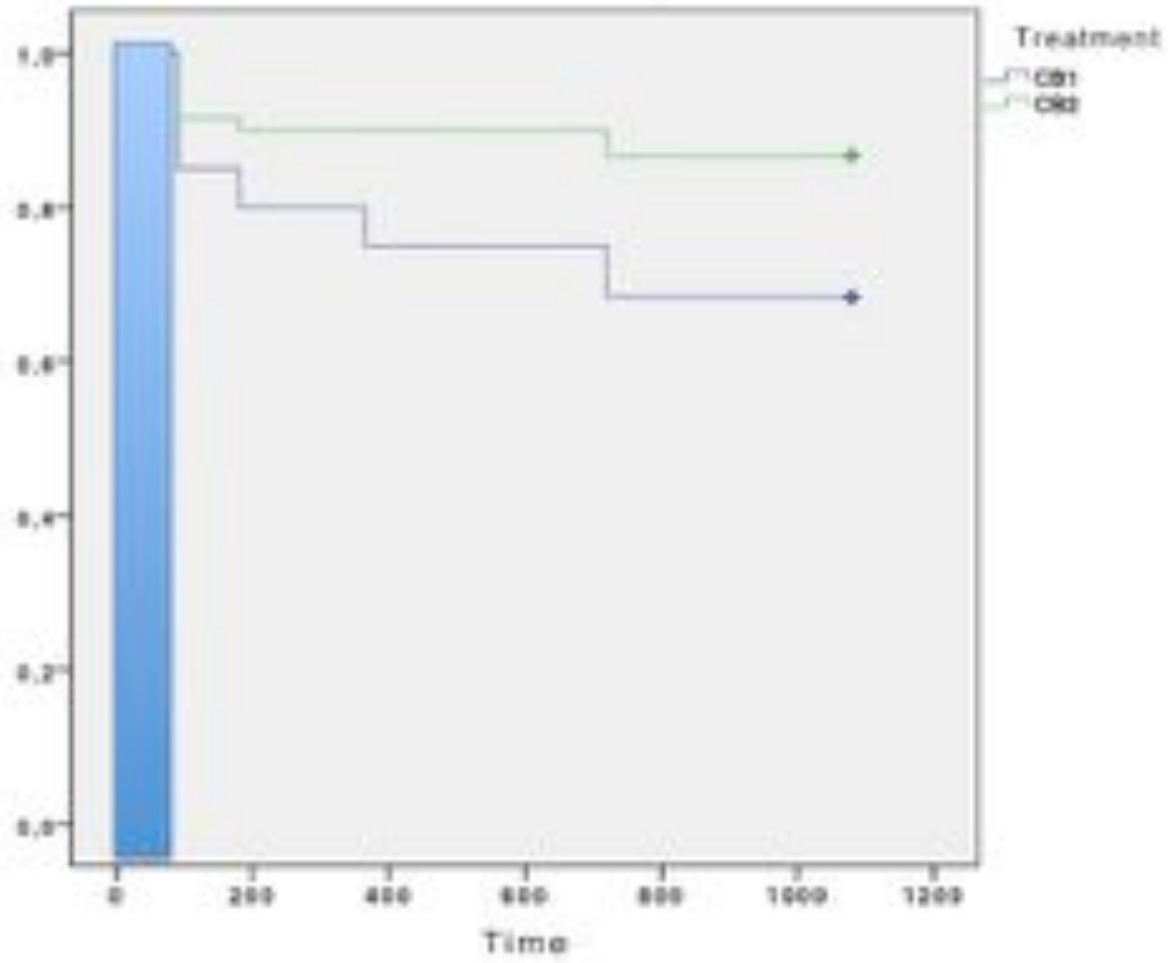
Cryoballoon: Single Center experience



Complications	n (%)
Stroke / TIA	0
Pericardial effusion	3 (0.9%)
Cardiac tamponade	1 (0.3%)
Vascular injury	7 (2.1%)
PV stenosis	0
Phrenic nerve palsy (transient and persistent)	6 (1.8%)

Cryoballoon: first vs second generation

The ADV catheter compared to the first generation balloon allows to obtain a significantly higher success rate after a single PVI procedure during the long-term follow-up. Fluoroscopy and procedural times were significantly shortened using the ADV catheter. The overall long-term success was significantly different between the two groups (68.3 vs 86.7% respectively; *p* = 0.017)



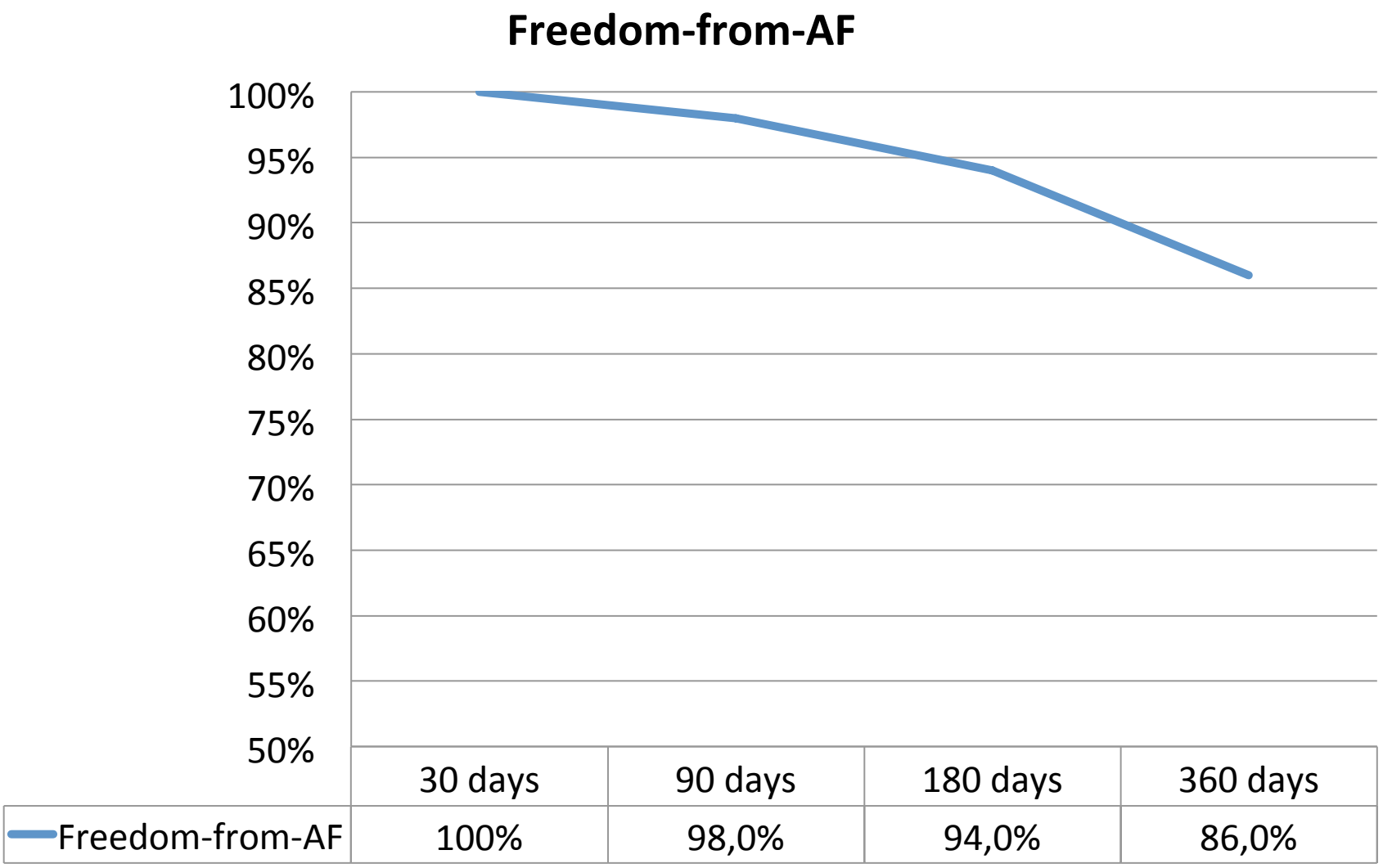
	CB 1st	CB 2nd	*p*
Procedure time, min (mean ± SD)	153.1 ± 32	102 ± 24.8	0.019
Fluoroscopy time, min (mean ± SD)	36.3 ± 16.8	14.2 ± 13.5	< 0.001

Moltrasio M, Tondo C et al. JICE 2013

Cardiac Arrhythmia Research Center-Centro Cardiologico

Cryoballoon: Single Center experience

Overall Results



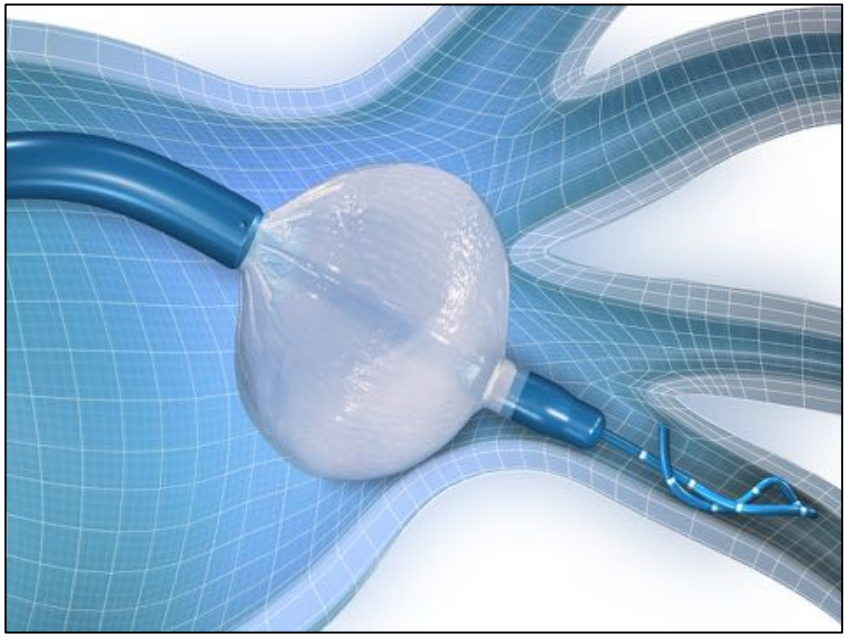
	30 days	90 days	180 days	360 days
Freedom-from-AF	100%	98,0%	94,0%	86,0%

Moltrasio M, Tondo C et al. JICE 2013

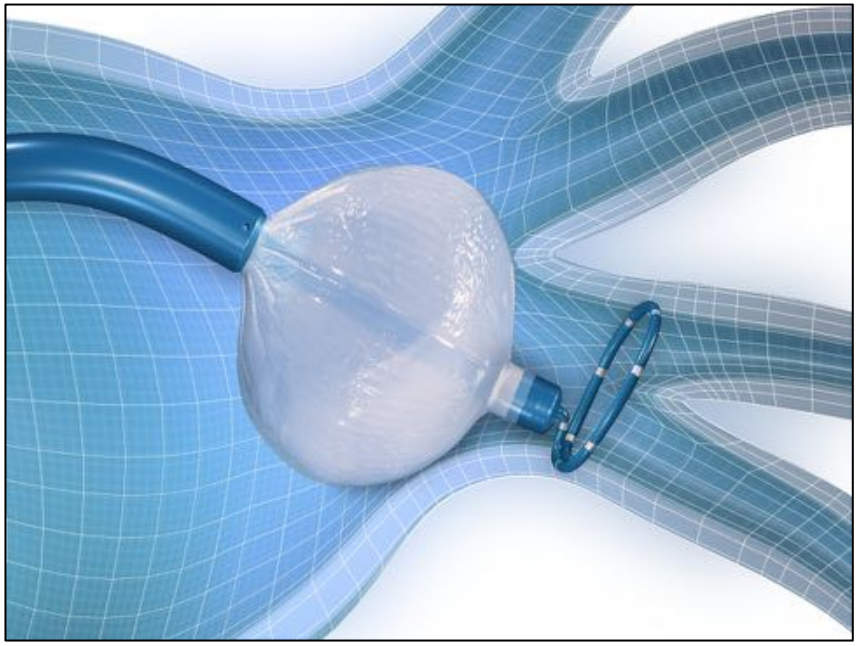
Shorter Tip Potential Benefit

Early PV Branching

Arctic Front Advance



Arctic Front Advance ST



- *Recording Rate: LSPV 76.6%; LIPV 60%; RSPV 73.3%; RIPV 50%*

Time-to-PVI assessment: third generation

after 30 pts…

- *LSPV 76.6%*
- *LIPV 60%*
- *RSPV 73.3%*
- *RIPV 50%*

LSPV	LIPV	RSPV	RIPV
1	1	1	0
1	1	1	0
1	1	1	1
0	0	1	0
1	0	1	1
1	1	0	0
1	0	1	1
0	1	0	1
1	0	1	0
0	0	0	0
1	1	1	1
1	0	1	0
1	0	1	1
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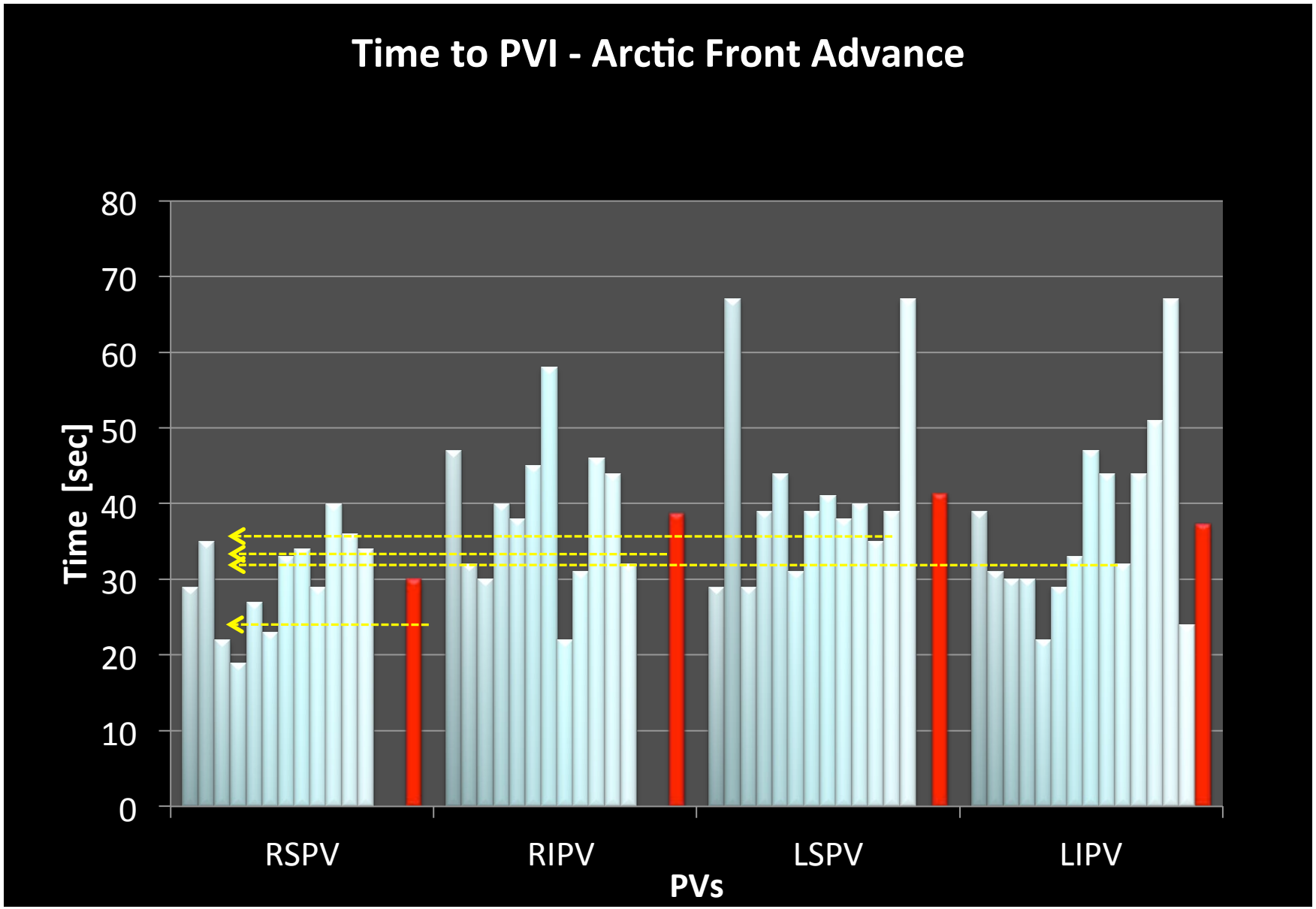
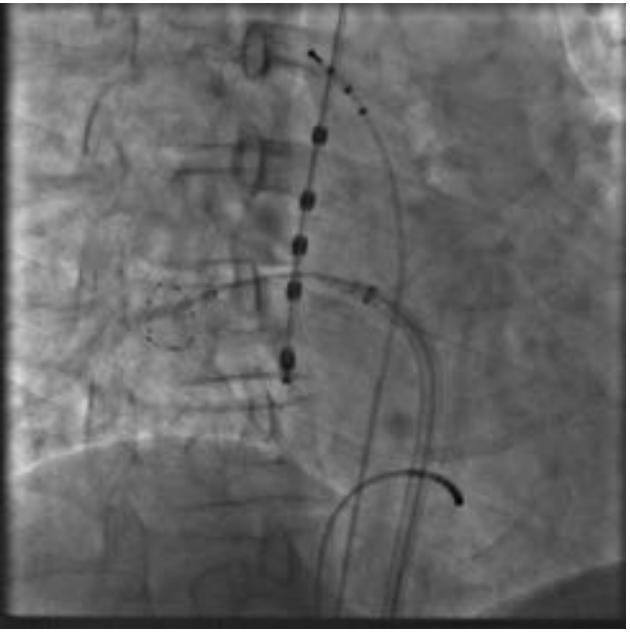
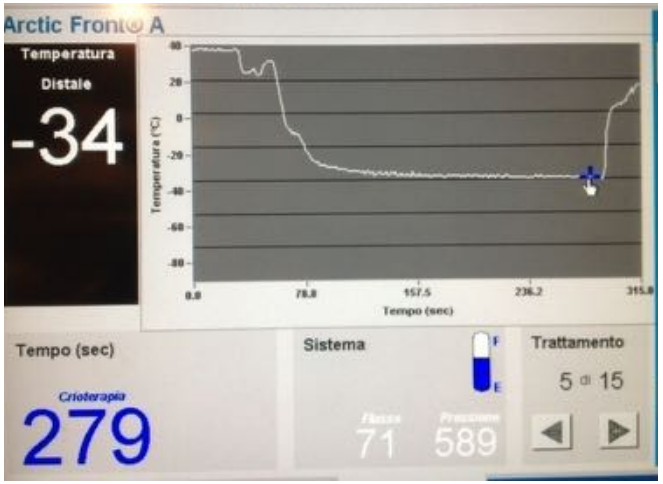

Time to PVI - Arctic Front Advance
Time [sec]
80
70
60
50
40
30
20
10
0
RSPV
RIPV
LSPV
LIPV
PVs

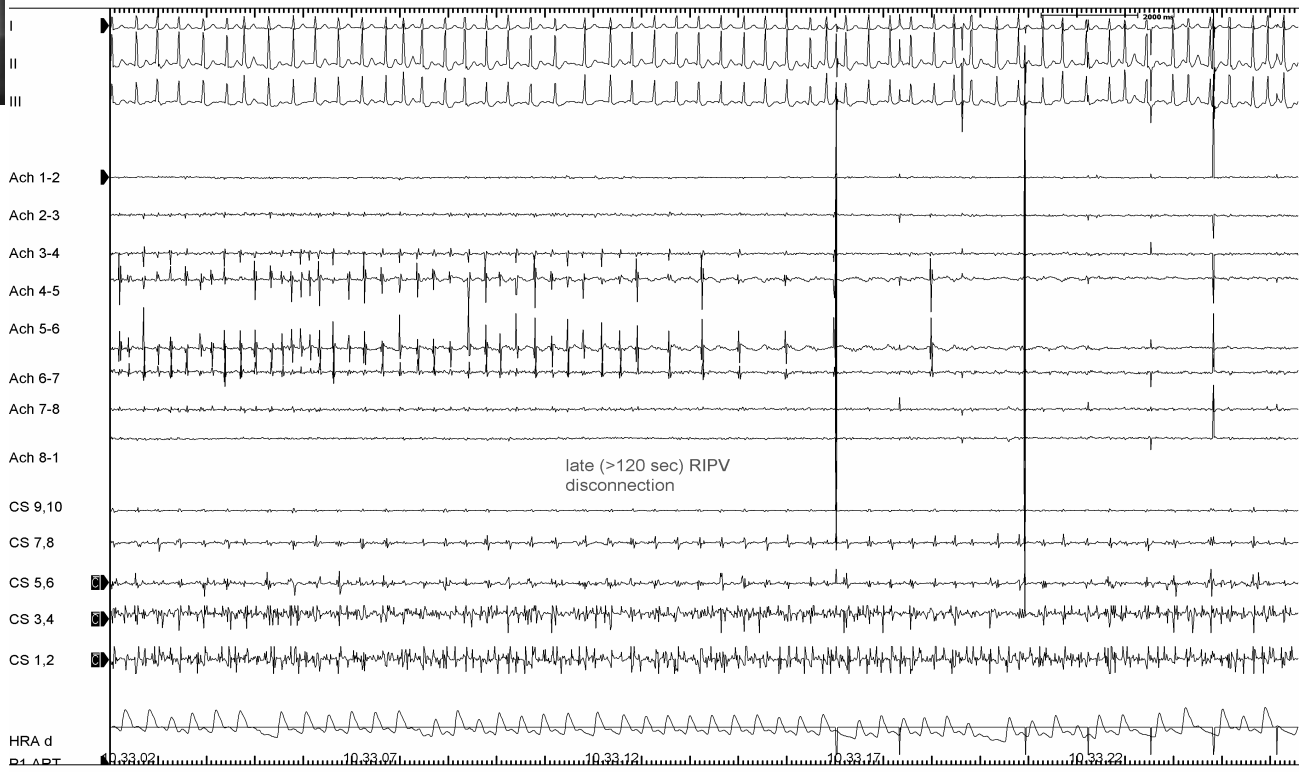
Cryoballoon: predictor of isolation?





Empiric predictor:

T°/Time 1:1 ratio
in the first 20”-30”



Durability of Pulmonary Vein Isolation with Cryoballoon Ablation: Results from the Sustained PV Isolation with Arctic Front Advance (SUPIR) Study

VIVEK Y. REDDY, M.D.,* LUCIE SEDIVA, M.D.,† JAN PETRU, M.D., PH.D.,† JAN SKODA, M.D.,† MILAN CHOVANEC, M.D.,† ZITA CHITOVOVA, M.D.,† PAOLA DI STEFANO, PH.D.,‡ ETHEL RUBIN, PH.D.,§ SRINIVAS DUKKIPATI, M.D.,* and PETR NEUZIL, M.D., PH.D.†

...t. Sinai Hospital, New York, New York, USA; †Homolka Hospital, Prague, Czech ...dtronic Clinical Research Institute, Milan, Italy; and §Medtronic Inc., Minneapolis, Minnesota, USA

2015

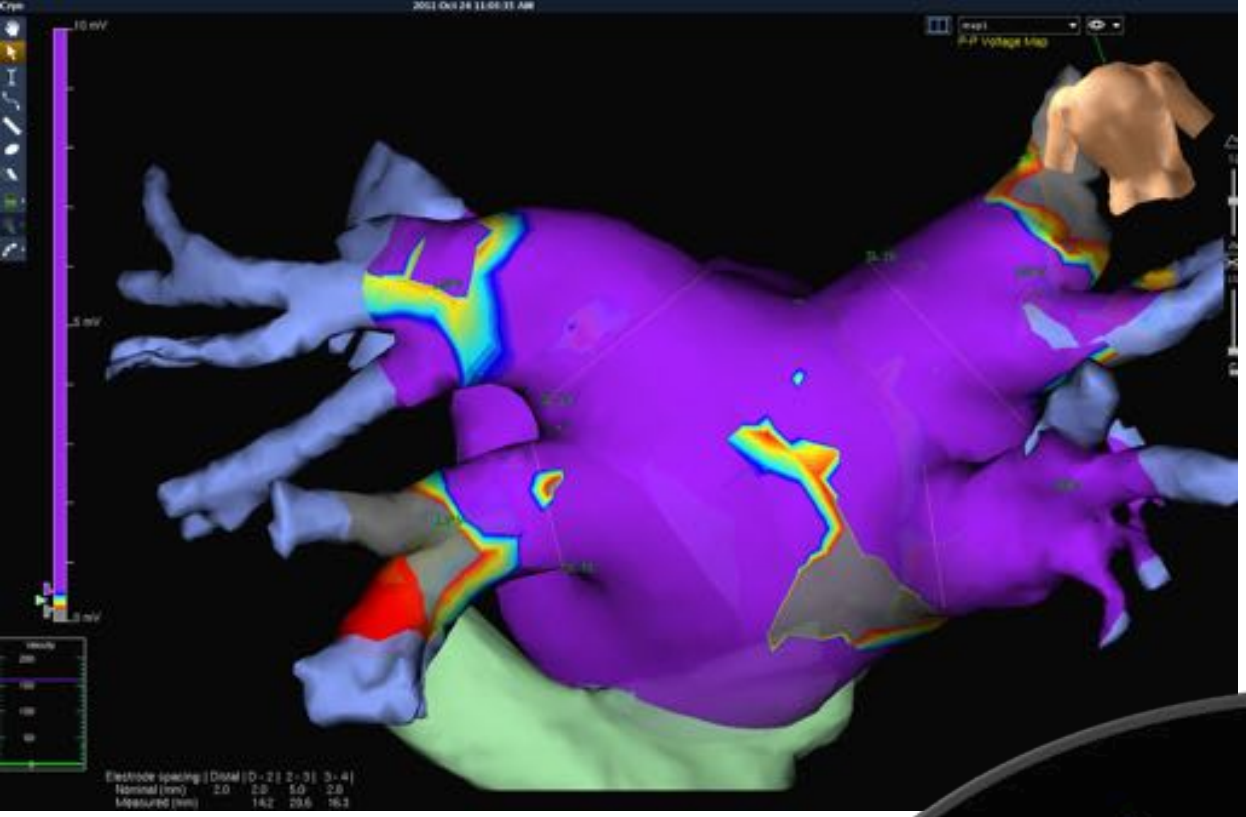
TABLE 5
PV Reconnections and Clinical AF Recurrence

Subject ID	Remapped	No. of PVs with Gaps	Location of Gap(s)	Clinical AF Recurrence
1	Yes	0		No
2	Yes	0		No
3	No	ND		ND
4	Yes	0		No
5	Yes	0		No
6	Yes	0		No
7	Yes	3	LSPV ridge area, LIPV anterior LAA area, RSPV posterior superior area	Yes
8	Yes	0		No
9	Yes	0		No
10	Yes	0		No
12	Yes	0		No
13	Yes	1	RIPV inferior aspect	ND
14	Yes	2	RSPV anterior/middle aspect, RIPV inferior aspect	Yes
15	Yes	0		No
15	Yes	0		No
17	No	ND		ND
18	Yes	0		No
19	Yes	0		No
20	Yes	0		No
21	Yes	0		No
22	Yes	1	RIPV inferior aspect	No

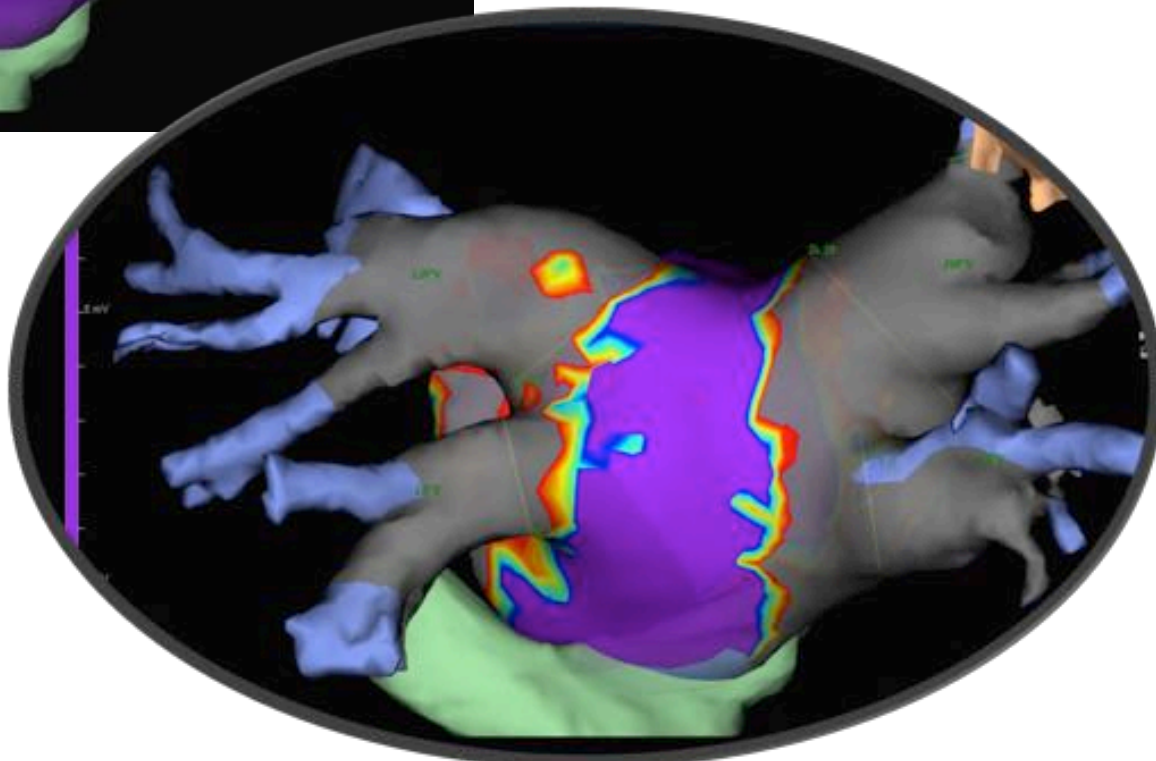
ND = not determined.

91% of PVs still isolated at 3 months check

Good correlation between AF recurrences and gaps



CryoAblation



Post-CryoAblation

Voltage Map

medication. As demonstrated by preprocedural CT/M
was significant interpatient and intrapatient variability
sizes: left inferior PV, 12.5 to 23.0 mm (mean, 17.2±
left superior PV, 13.0 to 23.0 mm (17.8±2.4 mm); rig
PV, 14.0 to 24.0 mm (17.9±2.1 mm); right superior I
24.0 mm (19.8±3.1 mm); and left common PV, 23.

Clinical Phase: Treatment Parameters

The total procedure time was 334±112 minutes,
278±91 minutes involved deployment and use of

Clinical Phase

Study Design

The study was a prospective, open-label, nonrandomiz
study of patients with symptomatic, recurrent, paroxys
had previously failed at least one class I or III antiarrh
Patients were included if they met the following criteria
and 75 years of age, ECG documentation of AF in the pr
at least 2 symptomatic AF episodes lasting >1 minu
hours in the prior 2 months. The major exclusion crite

This study introduces experimental feasibility and early clinical experience for a novel paradigm to AF catheter ablation:
direct endoscopic visualization.

Directly visualize the tissue being targeted for ablation, an approach moving ever so closer to approximating the surgical experience.

Pulmonary Vein Isolation Using a Visually Guided Laser Balloon Catheter

The First 200-Patient Multicenter Clinical Experience

Circulation
Arrhythmia and Electrophysiology

Srinivas R. Dukkipati, MD; Karl-Heinz Kuck, MD; Petr Neuzil, MD, PhD; Ian Woollett, MD; Josef Kautzner, MD, PhD; H. Thomas McElderry, MD; Boris Schmidt, MD; Edward P. Gerstenfeld, MD; Shephal K. Doshi, MD; Rodney Horton, MD; Andreas Metzner, MD; Andre d'Avila, MD, PhD; Jeremy N. Ruskin, MD; Andrea Natale, MD; Vivek Y. Reddy, MD

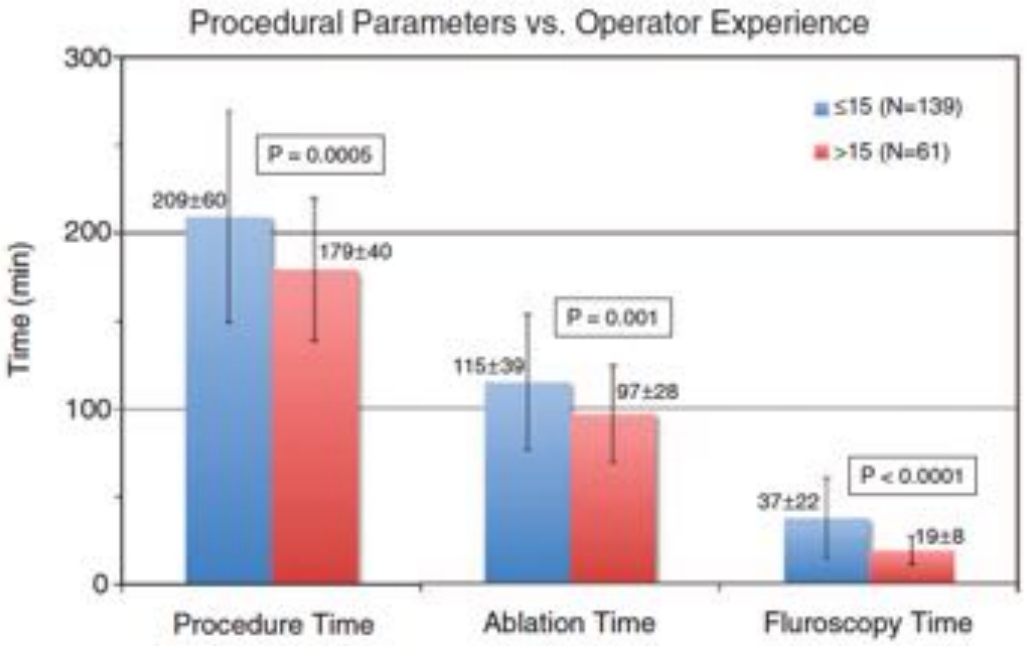


Table 2. Ablation Data (N=200)

No. of PVs isolated, n (%)	761/770 (98.8)
No. of PVs isolated on first attempt, n (%)	604 (78.4)
No. of attempts to isolate/PV, mean	1.3
No. of ablation lesions per patient	147±35
No. of catheters per patient	1.07
Fluoroscopy time, min (limits)	31±21 (3–135)
Laser ablation time, min (limits)	108±36 (34–236)
Procedure time, min (limits)	200±54 (85–358)

PV indicates pulmonary vein.

Table 5. VGLA-Related Complications

Complication Types	
Phrenic nerve injury	5 (2.5%)
Transient ischemic attack	0 (0%)
Stroke	0 (0%)
Cardiac tamponade	4 (2%)
Atrioesophageal fistula	0 (0%)
Bleeding	
Major	3 (1.5%)
Minor	7 (3.5%)

VGLA indicates visually guided laser ablation catheter.

Conclusions—In this multicenter experience of the first 200 patients treated with the VGLA catheter, PV isolation can be achieved in virtually all patients using a single VGLA catheter with an efficacy similar to radiofrequency ablation. (***Circ Arrhythm Electrophysiol*. 2013;6:467-472.**)

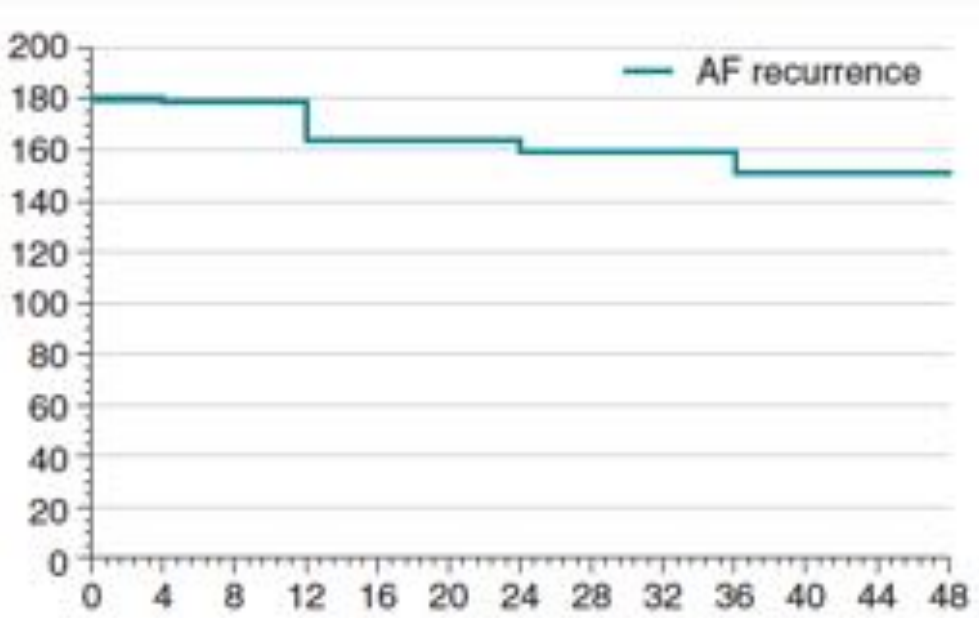
Visually guided laser ablation: a single-centre long-term experience

Lucie Šedivá[1]*, Jan Petrů[1], Jan Škoda[1], Marek Janotka[1], Milan Chovanec[1], Vivek Reddy[2], and Petr Neužil[1]

AF type	Number of patients	Percentage	Mean duration
Paroxysmal	178	91.75%	60.73 (11–300) months
Persistent	16	8.25%	62.75 (12–200) months

Total number of veins targeted	698
Number of common veins	23
Procedure time	226 (90–360) min
Fluoroscopy time	20.4 (6–42) min
Total ablation time per patient	121.6 min (36–157)
Average time application per vein	33.6 min
% of veins isolated acutely	99.2%
% of veins isolated at first attempt	95.3%

Complication	Occurrence	Percentage
Stroke/TIA	1	0.51%
Tamponade/pericardial effusion	1	0.51%
Acute phrenic nerve injury	4	2.06%
Persistent phrenic nerve injury (>6 months)	0	0%
Vascular injury	6	3.09%
PV stenosis	0	0%
Atrio-oesophageal fistula	0	0%



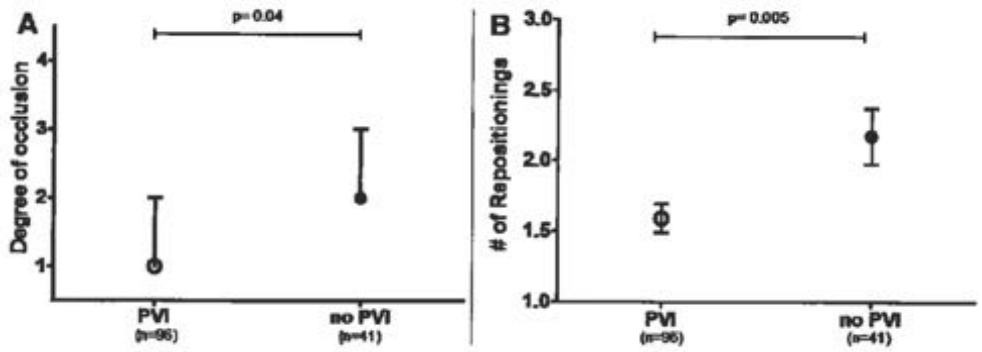
Visually Guided Sequential Pulmonary Vein Isolation: Insights into Techniques and Predictors of Acute Success

BORIS SCHMIDT, M.D., MELANIE GUNAWARDENE, M.D., VERENA URBAN, M.D., MEHMET KULIKOGLU, M.D., BRITTA SCHULTE-HAHN, M.D., BERND NOWAK, M.D., STEFANO BORDIGNON, M.D., and KR J. CHUN, M.D.

Predictor of acute isolation:

- degree of PV occlusion
- number of catheter repositionings

but not total ablation energy or the number of laser applications. Conduction gaps were detected at sites of suboptimal occlusion as well as esophageal temperature elevations.



Optimal PV occlusion and few controlled repositionings facilitate reproducible electrical PVI

77% of pts free from any tachyarrhythmia off AADs

Cardiac Arrhythmia Research Center-Centro Cardiologico

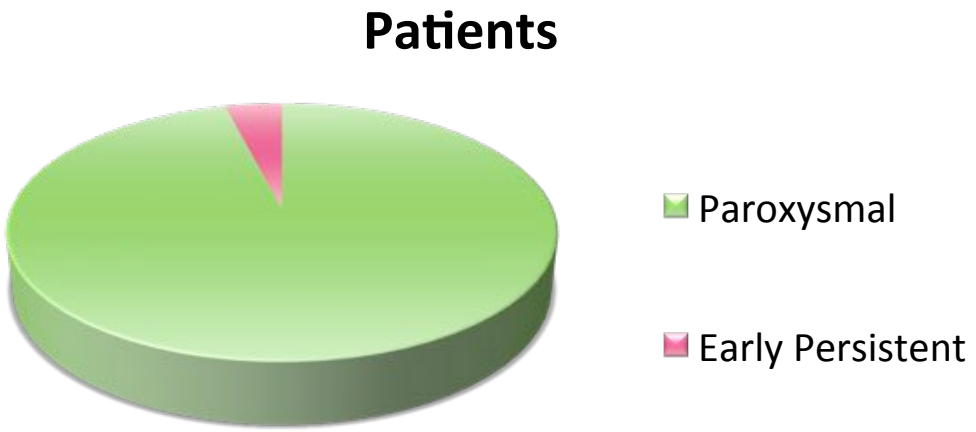
Single Center experience

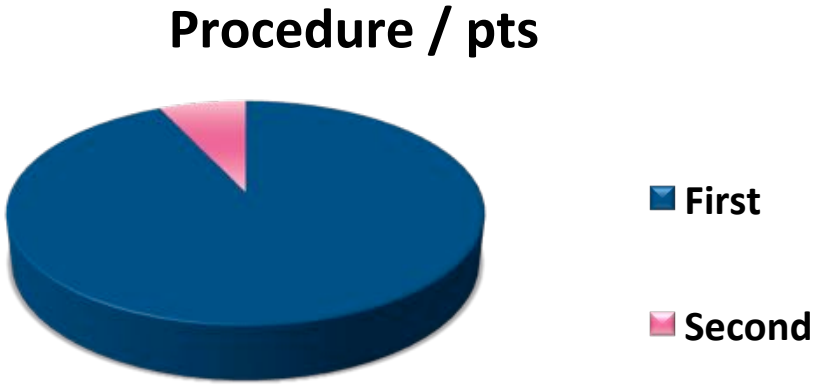
64 patients

49♀ 15♂

mean age 58 yo

CAD	13.2 %
HCM	1.9 %
Cardiac surgery	3.7 %
Valve disease	5.6 %
LA area (mean±SD)	21.7±4.7
LVEF (mean±SD)	62±6.8
AADs failure	96.3 %
AADs / pts	1.4

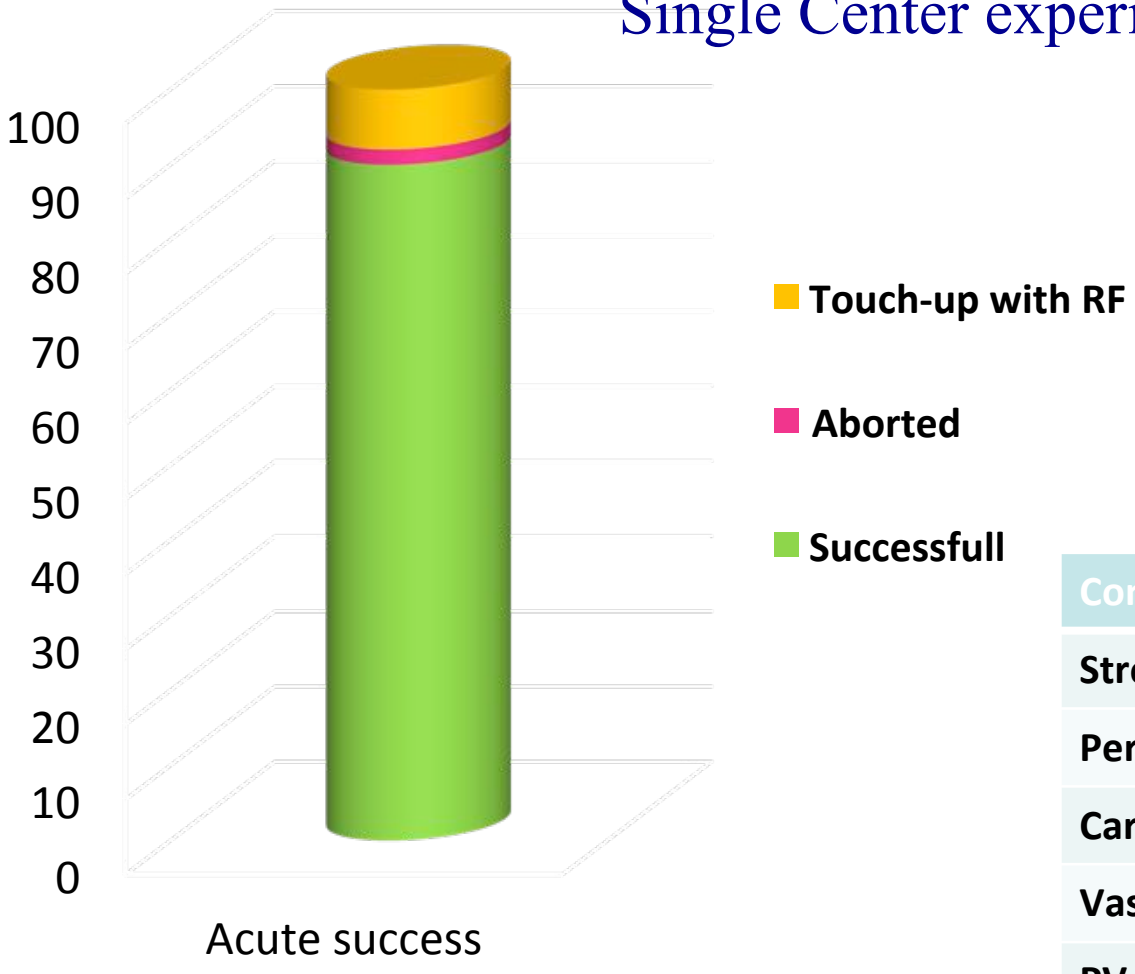




Visually-guided Laser Ablation

Cardiac Arrhythmia Research Center-Centro Cardiologico

Single Center experience

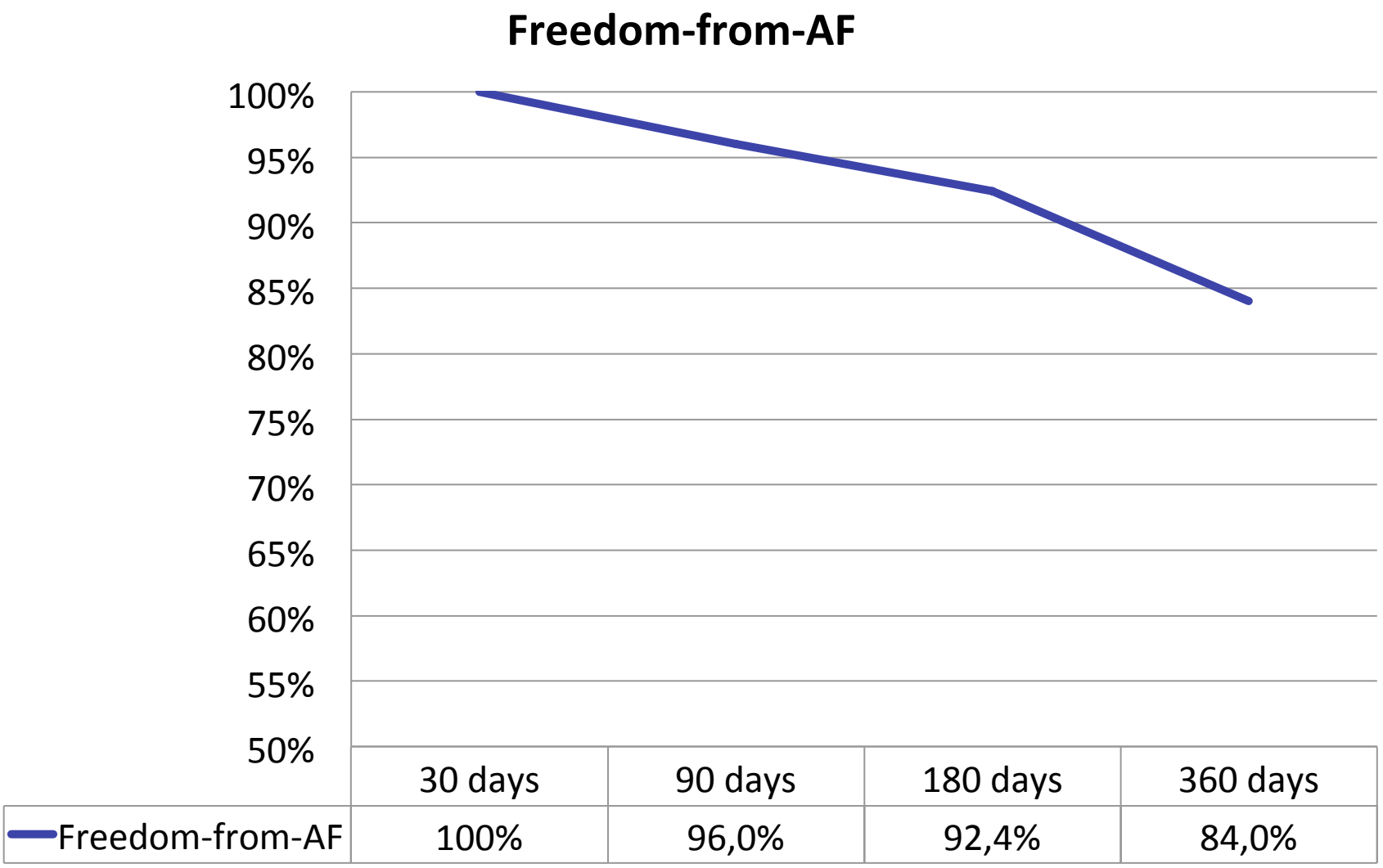


Complications	n (%)
Stroke / TIA	0
Pericardial effusion	1 (1.9%)
Cardiac tamponade	1 (1.9%)
Vascular injury	1 (1.9%)
PV stenosis	0
Phrenic nerve damage	0

Persona Data

Cardiac Arrhythmia Research Center-Centro Cardiologico

Single Center experience



	30 days	90 days	180 days	360 days
Freedom-from-AF	100%	96,0%	92,4%	84,0%

Multicenter Evidence of Durable PVI

86% of > 200 Remapped Veins Chronically Isolated

The durability of pulmonary vein isolation using the visually guided laser balloon catheter: Multicenter results of pulmonary vein remapping studies

Srinivas R. Dukkipati, MD,* Petr Neuzil, MD, PhD,† Josef Kautzner, MD, PhD,‡ Jan Petru, MD,† Dan Wichterle, MD,‡ Jan Skoda, MD,† Robert Cihak, MD,‡ Petr Peichl, MD,‡ Antonio Dello Russo, MD, PhD,§¶ Gemma Pelargonio, MD, PhD,§ Claudio Tondo, MD, PhD,§¶ Andrea Natale, MD, FHRS,‖ Vivek Y. Reddy, MD*†

BACKGROUND The visually guided laser ablation (VGLA) catheter is a compliant, variable-diameter balloon that delivers laser energy around the pulmonary vein (PV) o doscopic visualization. While acute PV is be feasible, limited data exist regarding t

OBJECTIVE We sought to determine the following ablation using the balloon-ba

METHODS The VGLA catheter was evalu oxysmal atrial fibrillation (3 sites, 10 op septal puncture, the VGLA catheter was deflectable sheath and inflated at the endoscopic guidance, the 30° aiming ar the PV and laser energy was delivered t tiguous/overlapping manner. At ~3 mo for a PV remapping procedure.

RESULTS In 56 patients, 202 of 206 PVs (98%) were acutely isolated. At 105 ± 44 (mean ± SD) days, 52 patients returned for PV remapping at which time 162 of 189 PVs (86%) remained isolated and 32 of 52 patients (62%) had all PVs still isolated. On forming <10 vs ≥10 procedures, the d the percentage of patients with all e 73% vs 89% ($P = .011$) and 57% vs y. After 2 procedures and 12.0 ± 1.9 drug-free rate of freedom from atrial

lticenter, multioperator experience, h rate of durable PV isolation with a hat of radiofrequency ablation.

n: Ablation; Laser; Paroxysmal; Pulmo- alization

ABBREVIATIONS AF = atrial fibrillation; PV = pulmonary vein; VGLA = visually guided laser ablation

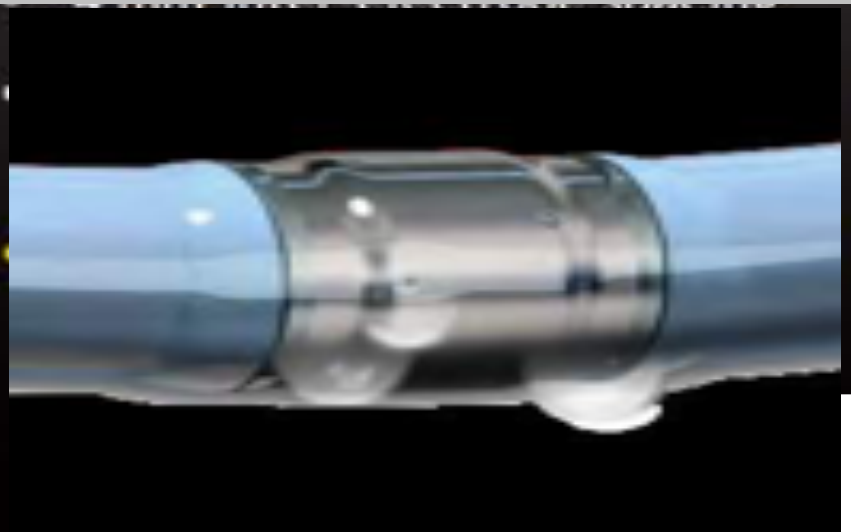
(Heart Rhythm 2012;9:919–925)

Effective PVI:
***98%* Acute Success**
And
***86%* Chronic Success**

nMARQ™ Catheter selection

nMARQ™ Circular

- Centered helical design
- Ten, 3 mm long irrigated electrodes
- 2.5mm effective surface area
- 10 irrigation ports per electrode
- 4 mm inter-electrode spacing
- Compatible with 8.5 Fr Sheath
- 20-35 mm loop diameter range



nMARQ

nMarq Circular catheter

nMARQ Circular: PV mapping techniques

Ostial

- Too much distal for ablation
- Optimal during FAM

Segmental

- Precise evaluation for segmental targeting
- PV carena ideal targetting/avoid Esophagus

Antral

- Ideal for small veins
- Extensive Lesion but requires stability

Final Outcomes of *REVOLUTION*: A Prospective, Multi-Center Clinical Study of Pulmonary Vein Isolation Using the nMARQ™ Circular and Crescent Multi-Electrode Irrigated Ablation Catheter (186 Pts)

- Acute effectiveness (PVI) in 98.7% of patients.

- Freedom from symptomatic AF in 70.8% at 8 months

- In the SNA group 13.9% of subjects exhibited asymptomatic CME with 4 occurrences in the nMARQ™ (21.1%) and 1 in the ThermoCool® group (5.9%).

Safety :

- **Esophageal monitoring**
- **Phrenic nerve mapping**

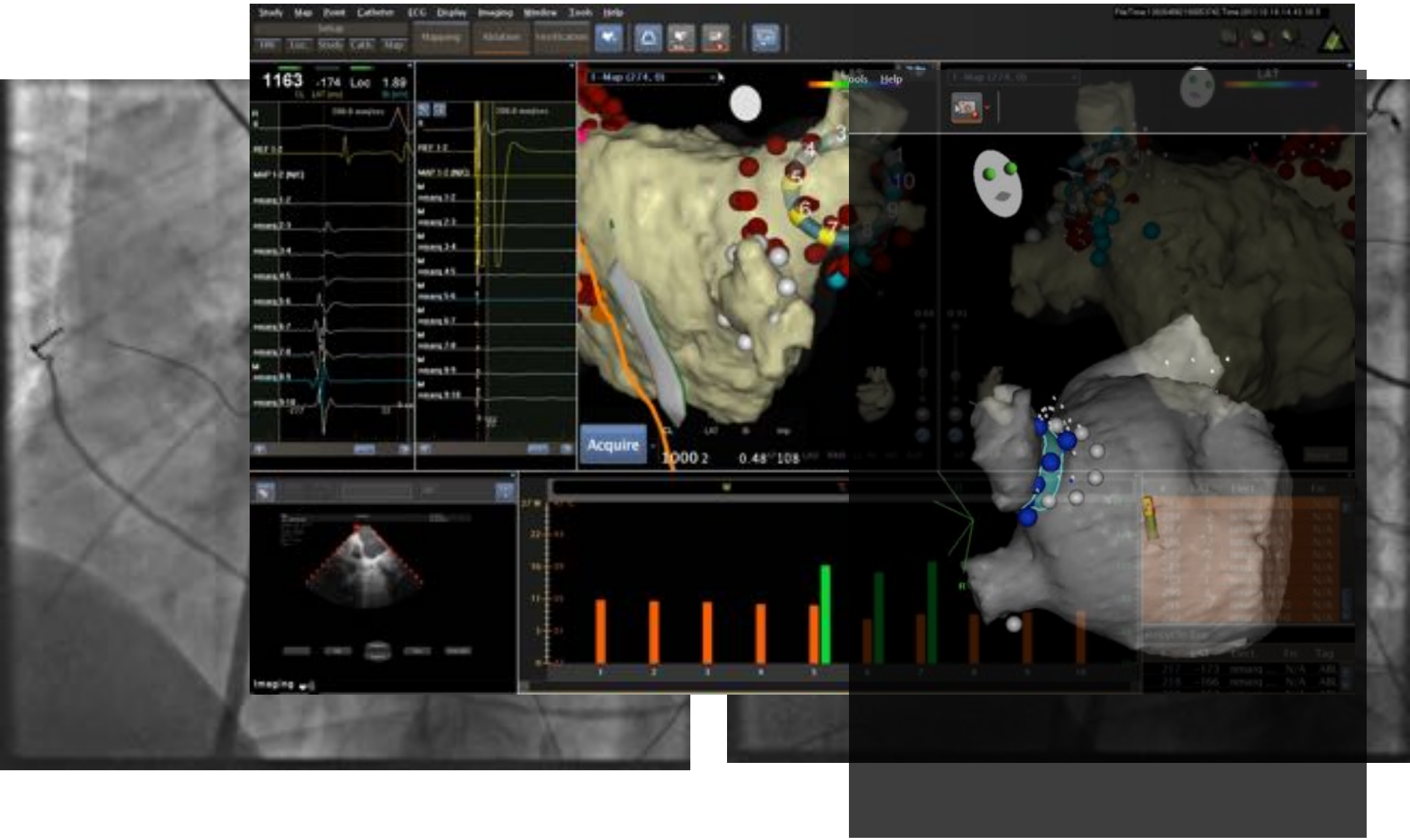
Biosense Webster
PART OF THE Johnson & Johnson FAMILY OF COMPANIES

URGENT FIELD SAFETY NOTICE
MEDICAL DEVICE – VOLUNTARY FIELD REMOVAL

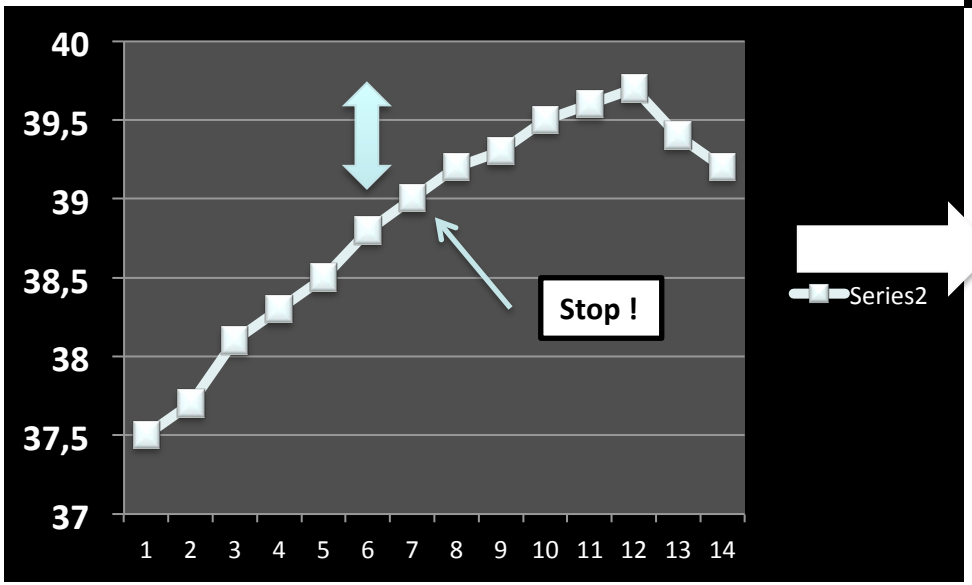
Biosense Webster, a division of Johnson & Johnson Medical NV/SA
nMARQ® Circular Irrigated Catheter
Catalog No: D132214

This removal is due to an increased number of complaints related to low temperature issues due to thermocouple malfunction of the nMARQ® Circular Irrigated Catheter, which occurred during the same time period as reports of three (3) deaths. Two (2) of these deaths have been confirmed to be due to Atrio-Esophageal Fistula (AEF).

Pacemapping of phrenic nerve



PROXIMITY LPVS/RIPV-ESOPHAGUS

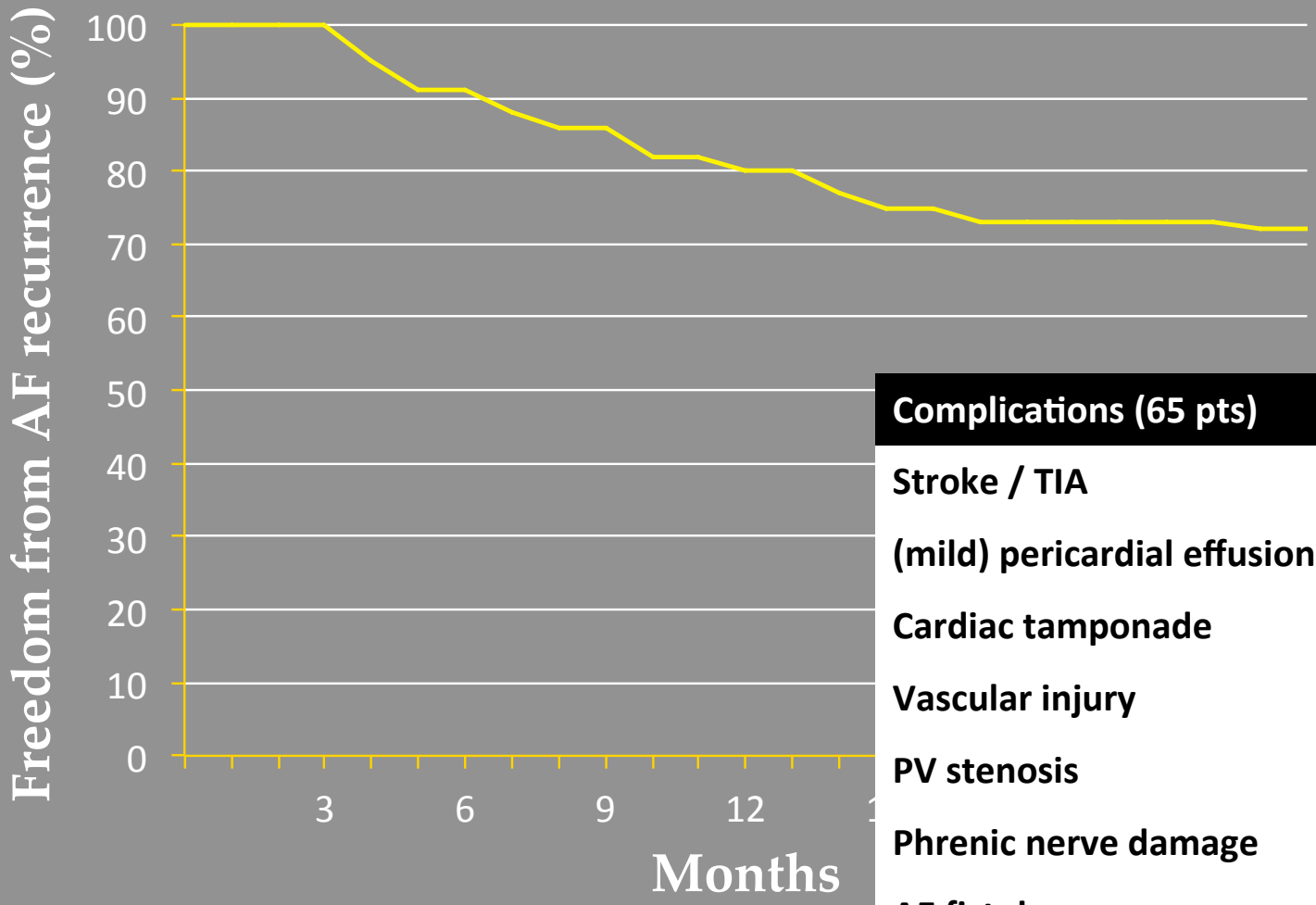


- Cut off value 39°
- Power setting at 15-18 targeting posterior wall

65 Pts; mean FU 20.6±9 m

Centro Cardiologico Monzino

Follow up



Complications (65 pts)	N
Stroke / TIA	0/1
(mild) pericardial effusion	2
Cardiac tamponade	0
Vascular injury	0
PV stenosis	0
Phrenic nerve damage	0
AE fistula	0
Esophageal lesion*	0

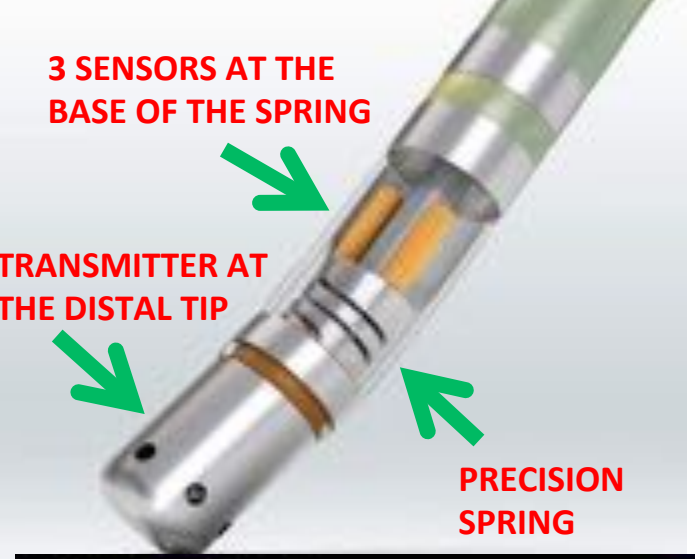
Contact Force Sensing Technology a compromise between efficacy and safety

Relationship Between Catheter Forces, Lesion Characteristics, "Popping," and Char Formation: Experience with Robotic Navigation System

LUIGI DI BIASE, M.D.,*,† ANDREA NATALE, M.D.,‡,§ CONOR BARRETT, M.D.,*
CARMELA TAN, M.D.,* CLAUDE S. ELAYI, M.D.,* CHI KEONG CHING, M.D.,*
PAUL WANG, M.D.,§ AMIN AL-AHMAD, M.D.,§ MAURICIO ARRUDA, M.D.,*
J. DAVID BURKHARDT, M.D.,* BRIAN J. WISNOSKEY, PH.D.,¶ PUNAM CHOWDHURY, M.D.,*
SHARI DE MARCO, R.N.,* LUCIANA ARMAGANIJAN, M.D.,* KENNETH N. LITWAK, M.D.,*
ROBERT A. SCHWEIKERT, M.D.,* and JENNIFER E. CUMMINGS, M.D.*

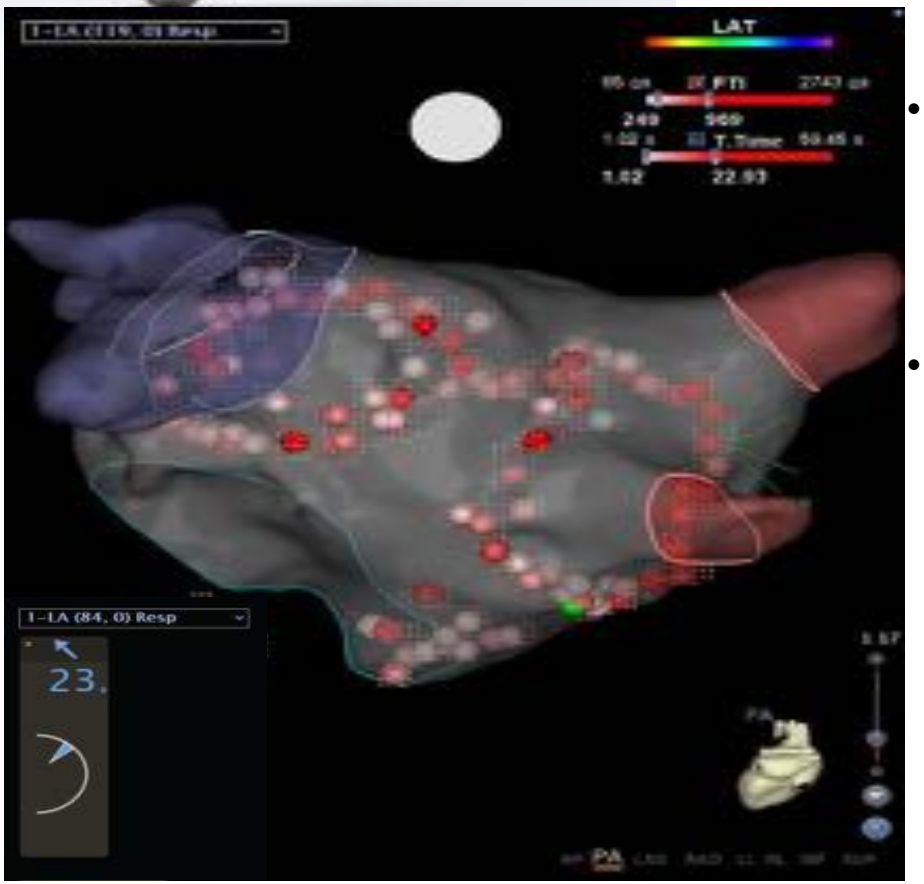
From the *Cleveland Clinic, Cleveland, Ohio, USA; †Department of Cardiology, University of Foggia, Foggia, Italy; ‡Texas Cardiac Arrhythmia Institute at St. David's Medical Center, Austin, Texas, USA; §Stanford University, Palo Alto, California, USA; and ¶Employee of Saint Jude Medical

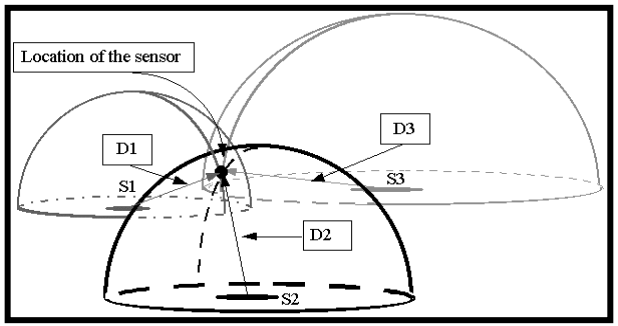
< 20 g/ cm^2	20-40 g/ cm^2	> 40 g/ cm^2
Non Transmural Lesion Ineffiective procedure	Transmural Lesion Effective Porcedure	Increased complications Effective Procedure with higher risk



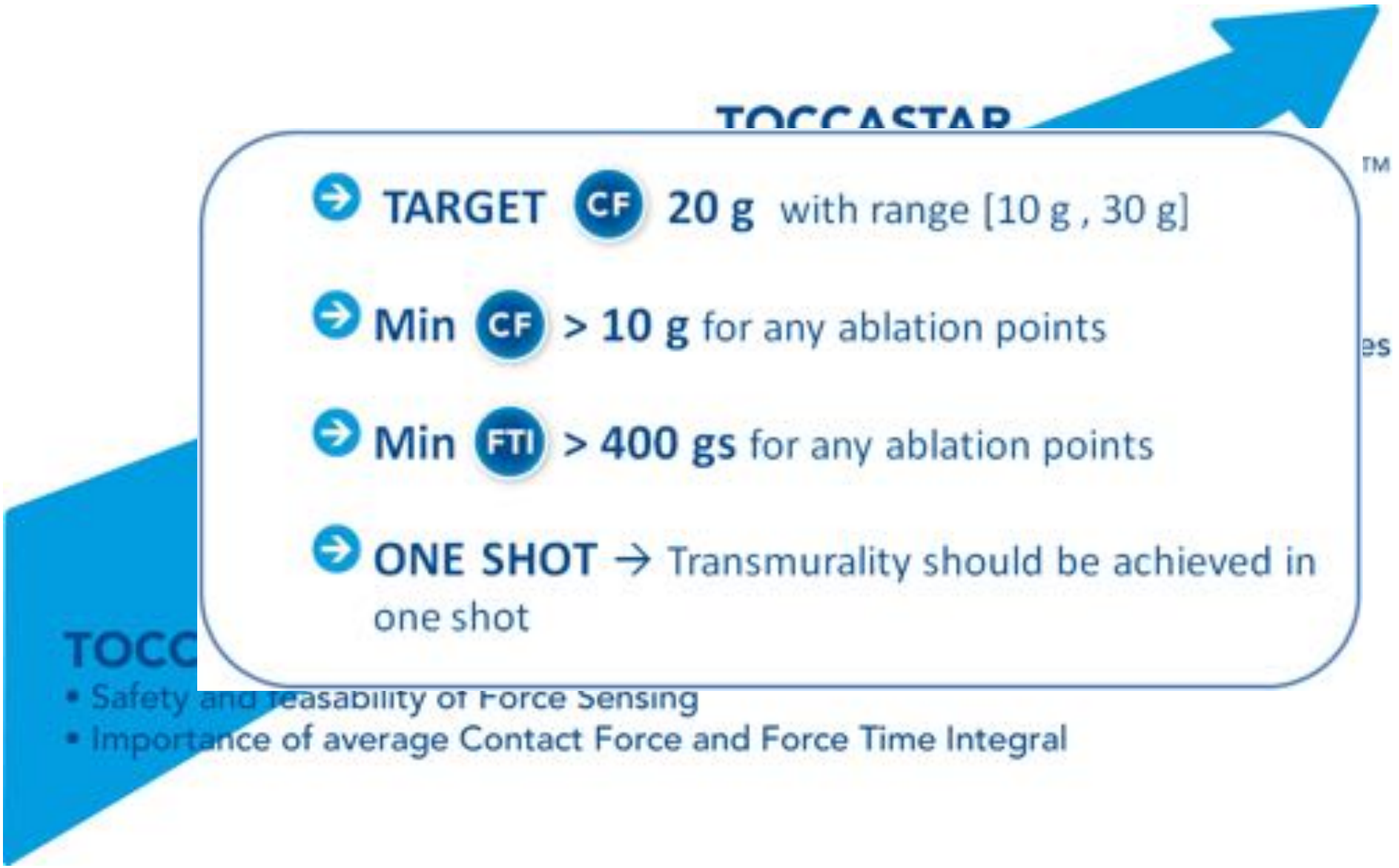
ThermoCool SmartTouch

- O-I-C 3.5 mm. Tiny spring at the distal tip connected to the proximal ring electrode..
- The force applied to the tissue results in the spring compression and/or stretching.
- Magnetic signal between a transmitter located in the tip and 3 receiving sensors at the base of the spring.
- The real-time force is measured in grams and can be displayed as a chronological curve in the independent “real-time graph” window on the CARTO 3 screen.
- The direction of the force can be displayed as a color-coded arrow vector on the tip of catheter image on the main view of the CARTO 3 system.

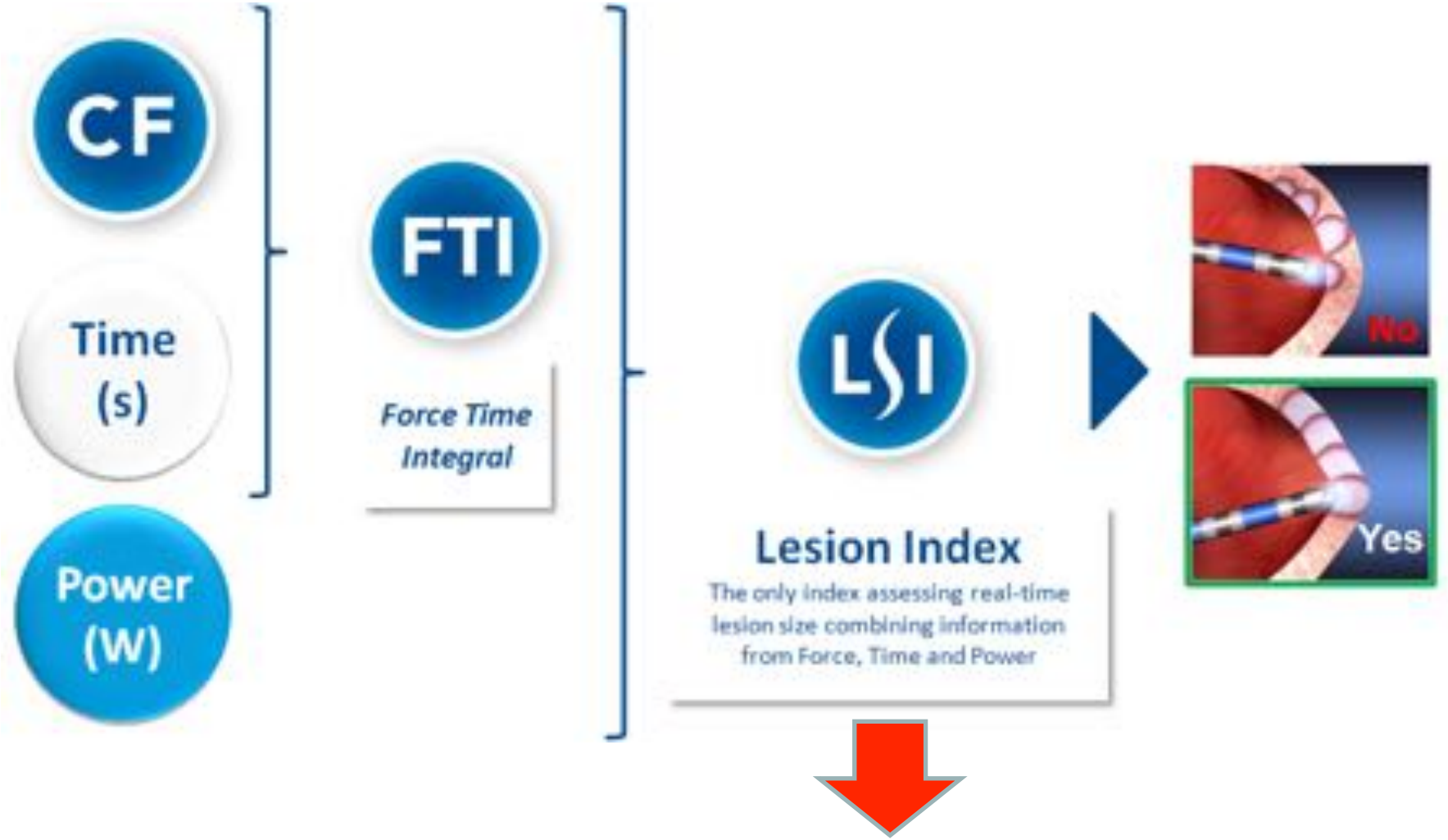




Increasing evidences



Force Time Integral (FTI) and Lesion Index (LSI™)



study[10] described in detail EGM morphological changes as being highly predictive of TL. Nevertheless, artefacts during RF delivery may render EGM morphological changes difficult to assess.

performed at the Princess Grace Hospital in Mona
gave written informed consent. Ablation strategy con
ential PV ablation with an endpoint of lasso-proven P

† The first two authors contributed equally to this paper.
* Corresponding author. Tel: +377 97 98 97 71; fax: +377 97 98 97 32. *E-mail address*: dglatcu@yahoo.com

energy (*D*), for transmural and non-transmural lesions. Outside values are excluded.

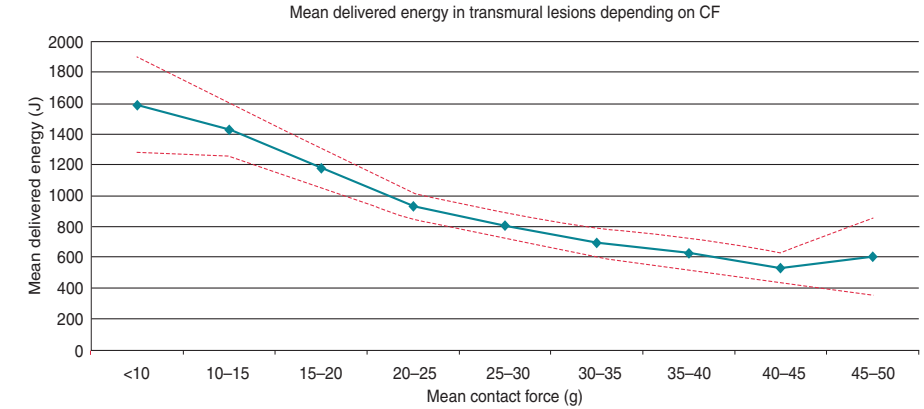


Figure 4 Mean delivered energy per RF pulse in the TL group, depending on the contact force (CF). Dashed lines represent the 95% confide interval. Mean delivered energy quickly decreases as the CF increases from <10 to 20–25 g. Between 20–25 and 35–40 g, mean delivered ene decreases slowly, whereas it remains stable above 40 g.

298 J with a CF of 20–25 g ($P = 0.002$ vs. 15–20 g); and 808 ± 302 J with a CF of 25–30 g ($P = 0.03$ vs. 20–25 g).

However, differences in delivered power between TL and NTL sites did not reach significance (34 ± 6.1 W for TL pulses vs. 32.6 ± 5.7 W for NTL pulses, $P = 0.06$). Impedance before RF was slightly higher in TL sites (167 ± 14.2 vs. 162.6 ± 14.8 Ω, $P = 0.01$), but end-pulse impedance was not significantly different (155.2 ± 18.8 Ω for TL pulses vs. 153.6 ± 14.3 Ω for NTL pulses, $P = 0.46$). The impedance drop was not discriminant for transmurality (9 ± 11.1 Ω for TL vs. 11.8 ± 16.6 Ω for NTL, $P = 0.14$).

minimal distance t
curve of the FTI w
positive predictive
and the negative p
FTI threshold (700
Se (0.39) and NPV

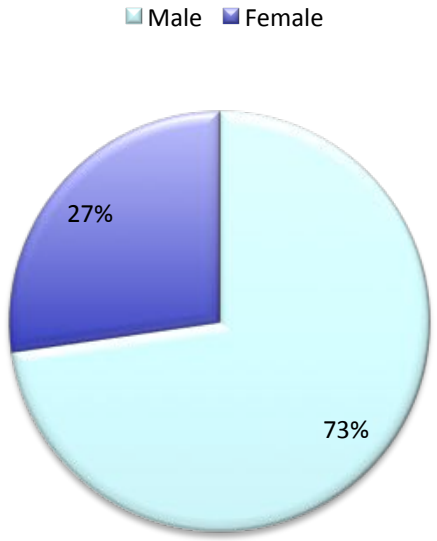
Smooth po

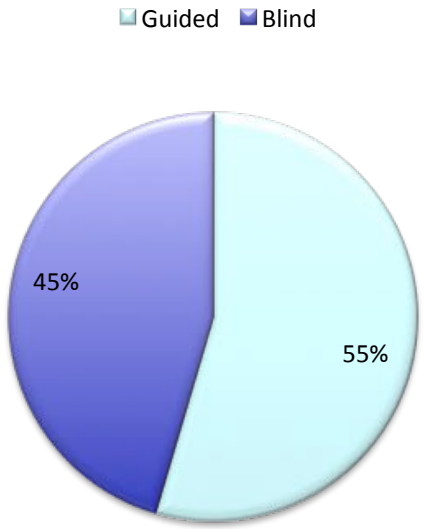
Subgroup analysis
tinated portions s

Tacticath LTI-FTI study

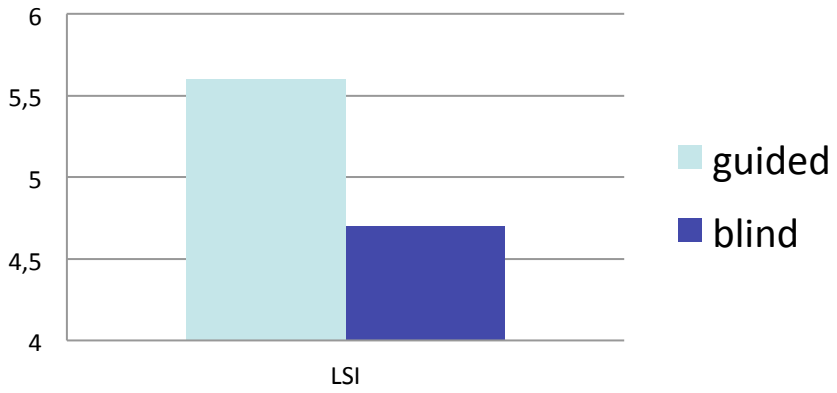
LSI-FTI Guided vs Blind procedure

n=33

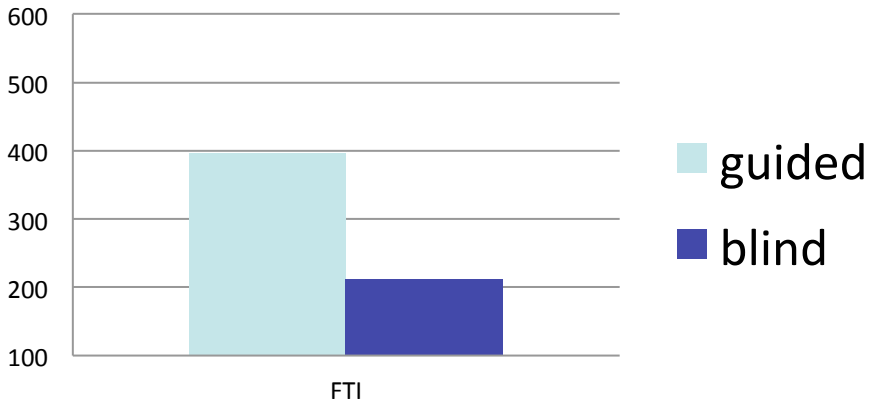




Average LSI per procedure



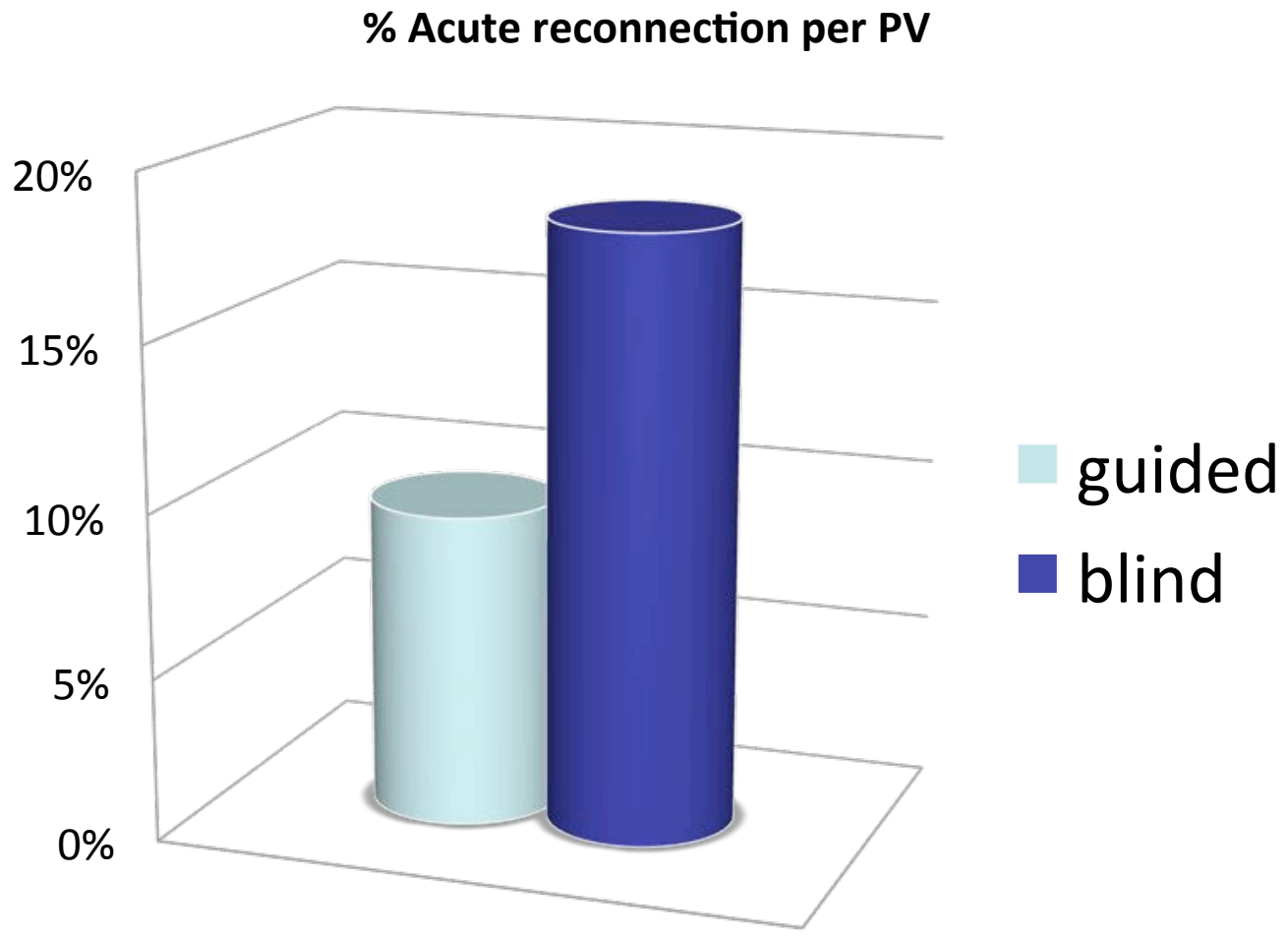
Average FTI per procedure



Personal data

Tacticath LTI-FTI study

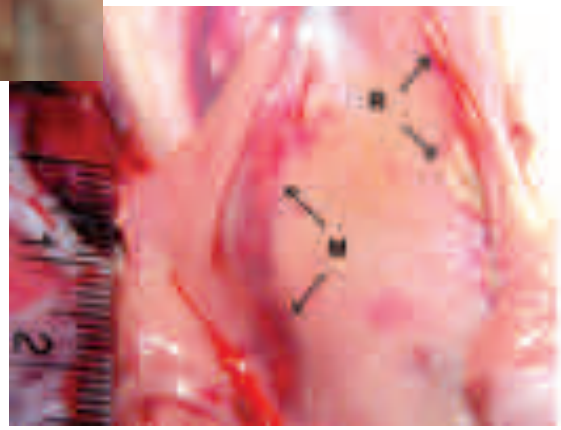
LSI-FTI Guided vs Blind procedure

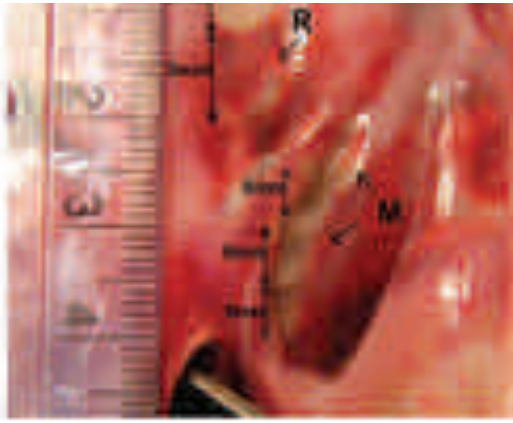


Personal data

Lessons from robotic AF ablation

Transmural and continuous lesions using the Robotic System (black line) compared to manual lesions (green line)





Robotic lesions (R) are necrotic and transmural, while manual lesions (M) appear haemorragic. On the right panel, endocardically, robotic lesions (R) are wider compared to manual lesions (M)

J Cardiovasc Electrophysiol **2009;20:1398-1404**

59
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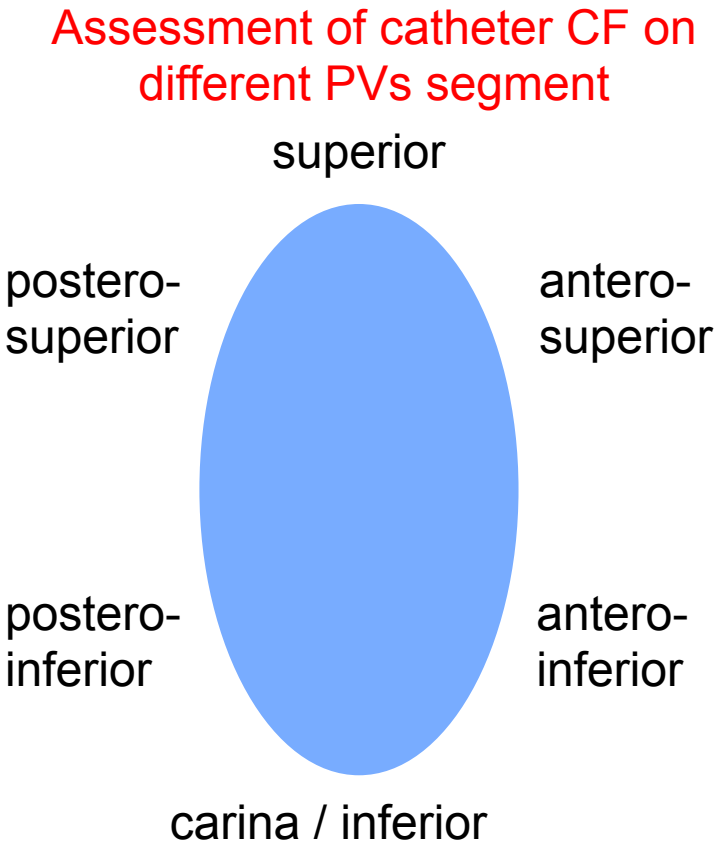
Aim of this study was to investigate the effect of RNS on CF using information provided by ThermoCool SmartTouch ablation catheter and to assess if CF values are increased when compared to manual approach. We sought also to determine if increased CF values could affect clinical follow-up.

Pts randomized 1:1 in 2 groups

- **Hansen + SmartTouch (40 pts)**
- **Manual + SmartTouch (40 pts)**



Personal data [under review]

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	Hansen (n=40)	manual (n=40)	*p*
Male sex, n (%)	32 (80)	24 (60)	0.12
Mean age (years)	61 ± 10	62 ± 9	0.51
Paroxysmal atrial fibrillation, n (%)	29 (72.5)	28 (70)	0.63
Persistent atrial fibrillation, n (%)	11 (27.5)	12 (30)	0.54
Left atrial diameter, (mm)	43 ± 8	41 ± 7	0.33
Diabetes mellitus, n (%)	1 (2.5)	2 (5)	0.53
Hypertension, n (%)	17 (42.5)	15 (37.5)	0.77
Hypercholesterolemia, n (%)	8 (20)	10 (25)	0.60
Hypertriglyceridemia, n (%)	-	-	-
Active smoking, n (%)	12 (30)	12 (30)	0.56
Body mass index, (Kg/m^2)	26 ± 2	26 ± 3	0.59
Coronary artery disease, n (%)	-	-	-
Previous ischemic stroke, n (%)	-	1 (2.5)	0.53
Chronic renal failure, n (%)	6 (15)	8 (20)	0.33
LVEF, (mean ± SD)	62 ± 6	61 ± 7	0.72
CHA2DS2-VASc	1.5 ± 1.3	1.6 ± 1.1	0.86

Personal data [under review]

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	Contact force on Left Pulmonary veins			Contact force on Right Pulmonary veins		
	Hansen (n=40)	manual (n=40)	*p*	Hansen (n=40)	manual (n=40)	*p*
Superior	26 (14-31)	18 (11-21)	0.004	26 (13-30)	18 (9-21)	0.002
Antero-superior	26 (14-32)	12 (9-14)	<0.001	23 (12-28)	10 (7-15)	<0.001
Postero-superior	23 (13-29)	15 (7-25)	0.001	24 (10-30)	13 (7-21)	<0.001
Carina	25 (12-28)	10 (7-15)	<0.001	26 (10-30)	12 (8-18)	<0.001
Antero-inferior	24 (16-28)	10 (8-13)	0.001	24 (11-28)	11 (8-17)	<0.001
Postero-inferior	23 (17-29)	11 (7-15)	0.02	23 (12-30)	10 (8-15)	<0.001
Inferior	21 (14-30)	9 (6-12)	<0.001	25 (11-28)	11 (8-14)	<0.001

Personal data [under review]

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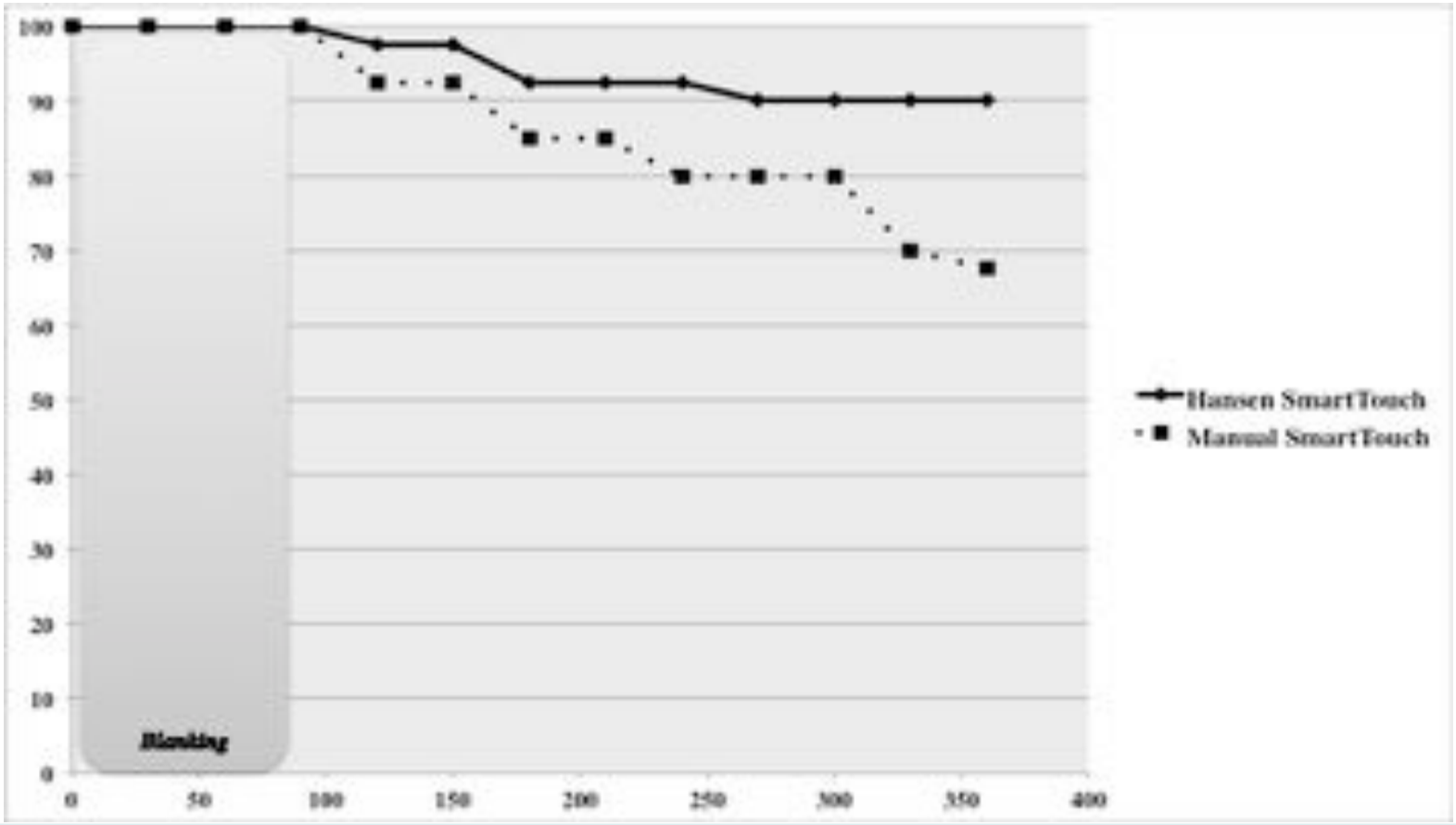


In this randomized study, concerning a mixed population of paroxysmal and persistent AF patients, we demonstrated that the use of ThermoCool SmartTouch ablation catheter with the RNS is associated with increased contact between the ablation catheter and myocardial tissue and to a lower AF recurrence rate at clinical follow-up.

Personal data [under review]

Electrical Reconnection After Pulmonary Vein Isolation Is Contingent on Contact Force During Initial Treatment

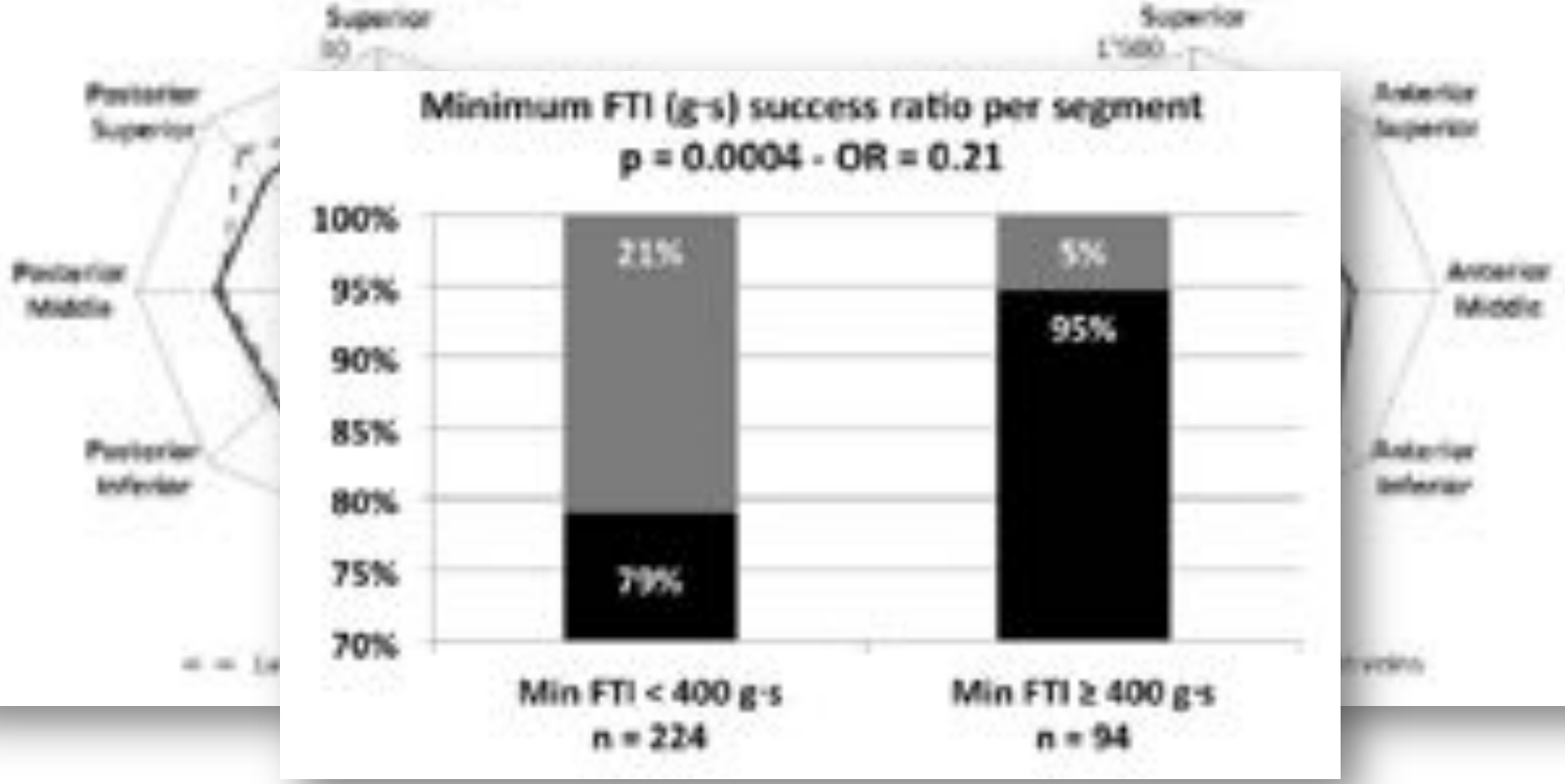
Results From the EFFICAS I Study

Petr Neuzil, MD, PhD; Vivek Y. Reddy, MD; Josef Kautzner, MD, PhD; Jan Petru, MD; Dan Wichterle, MD, PhD; Dipen Shah, MD; Hendrik Lambert, PhD; Aude Yulzari, MSc; Erik Wissner, MD; Karl-Heinz Kuck, MD, PhD, FHRS

2013

C Average Contact Force [g] per position
46 patients

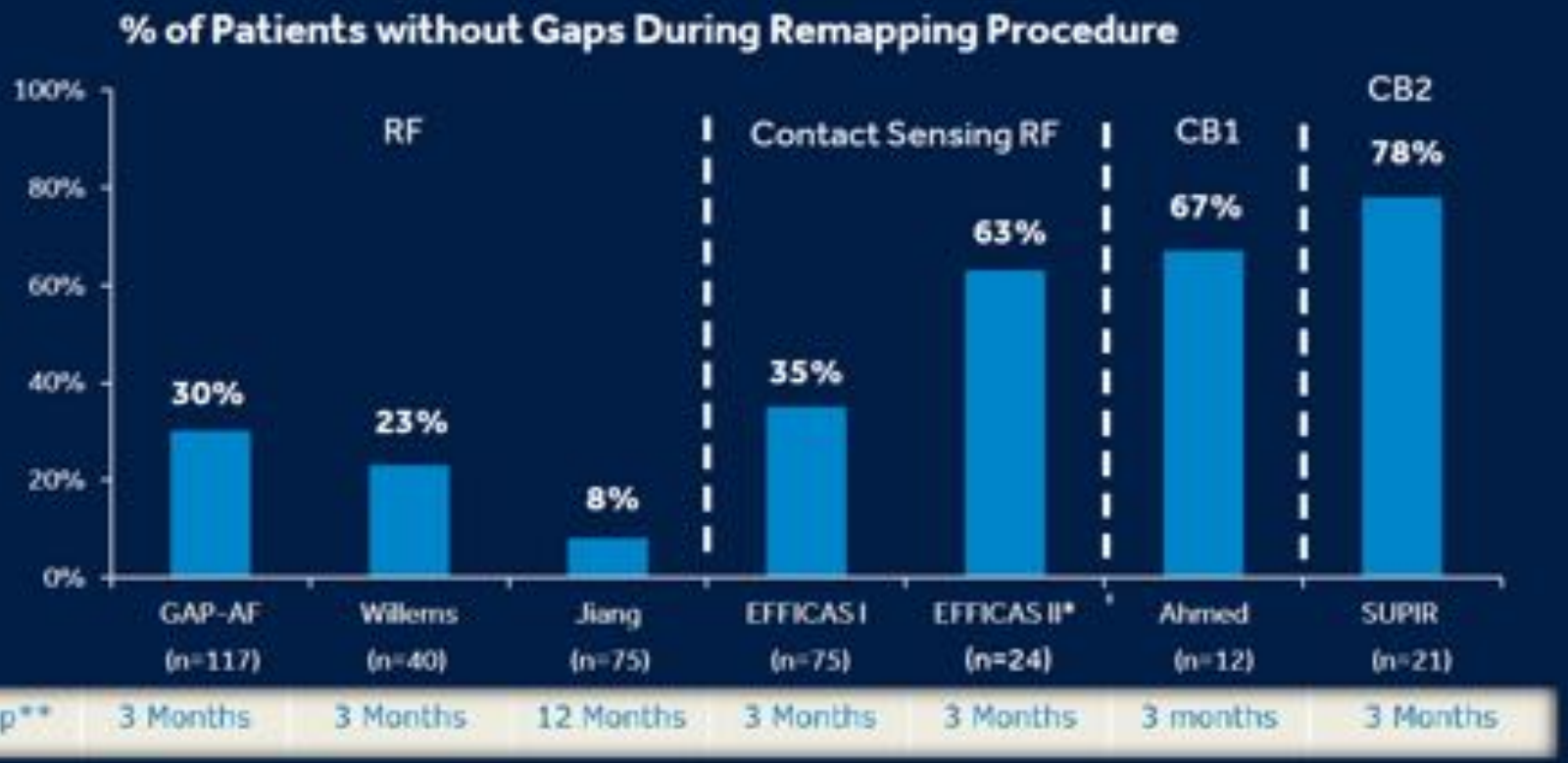
D Average FTI [g.s] per position
46 patients



PV LESION DURABILITY WITH RF AND CRYOBALLOON

STUDIES EVALUATING PV RECONDUCTION USING REPEAT ELECTROPHYSIOLOGY AND MAPPING AFTER THE INDEX PROCEDURE

CB1 = Arctic Front Cryoballoon
CB2 = Arctic Front Advance Cryoballoon



* Calculated rate from manuscript data reporting 9/24 patients with gaps.
** Time between index procedure and re-mapping procedure. All patients were evaluated regardless of clinical symptoms

1Late Breaking Clinical Trials session I at the EHRA EUROPACE 2013 meeting in Athens, Greece 2 Willems, et al. J Cardiovasc Electrophysiol. 2010; 21(10):1079-84; 3 Jiang, et al. Heart Rhythm. 2014;11(6):969-76; 4 Neuzil et al. Circ Arrhythm Electrophysiol. (3):327-35; 5 Kautzner, J. et al. Europace. 2015; In Press; 6 Ahmed, et al. J Cardiovasc Electrophysiol. 2010;21(7):751-7; 7 Reddy VY, et al. J Cardiovasc Electrophysiol. 2015 May;26(5):493-500.

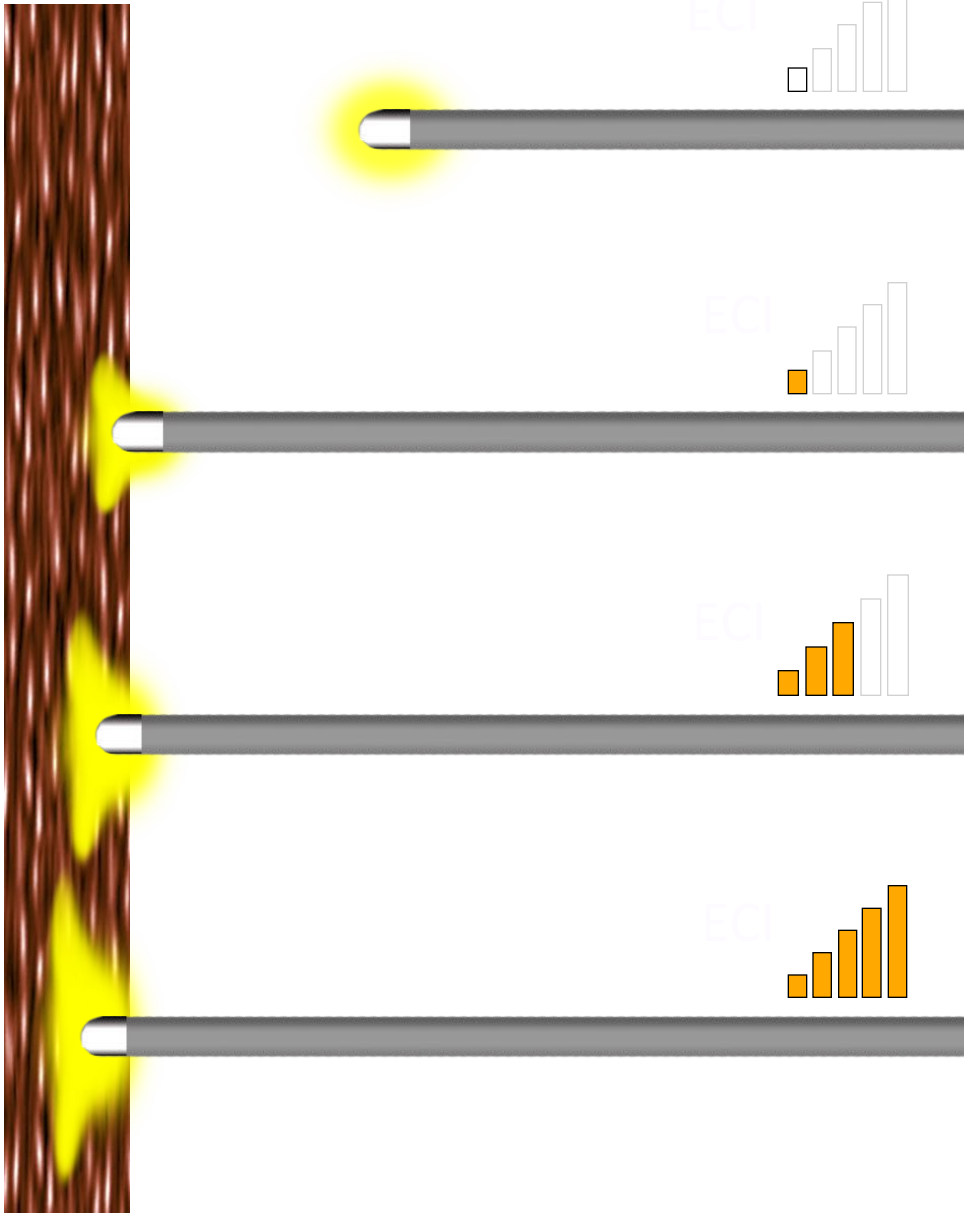
What ECI does

ECI measures the electrical coupling of the catheter and nearby tissue.

The detection is limited within 2 mm around the catheter tip.

- This is why ECI is a good predictor of therapeutic RF energy transfer to tissue.

ECI is independent of tip angle.



Simultaneous assessment of contact pressure and local Electrical Coupling Index using Robotic navigation

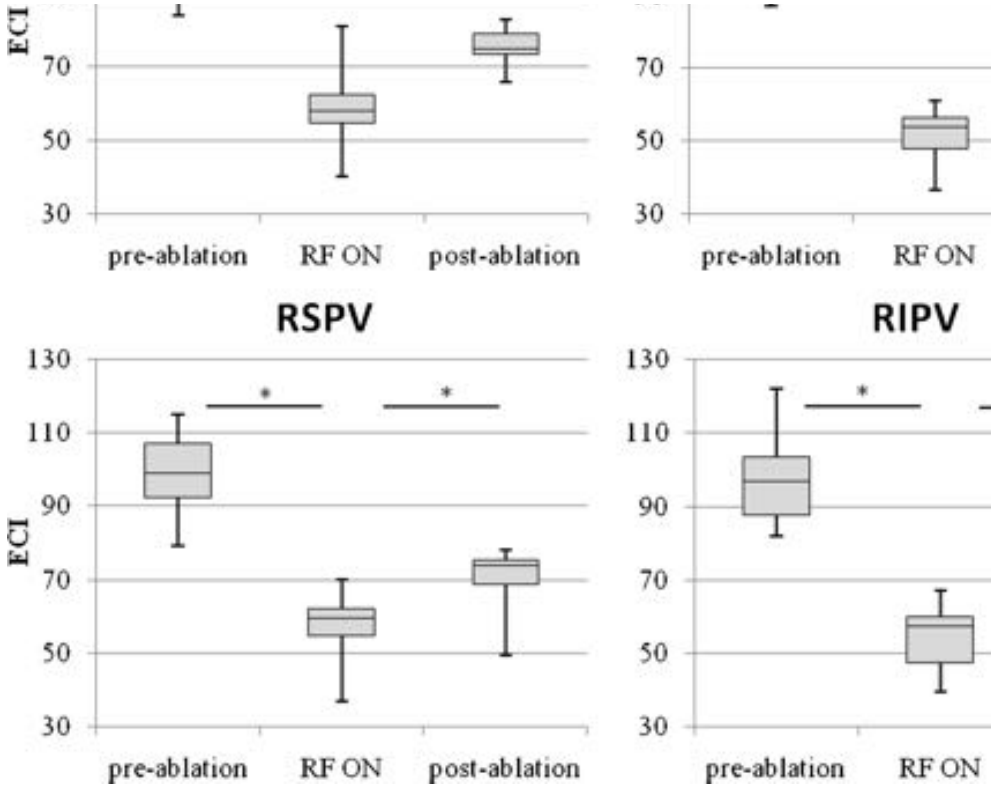
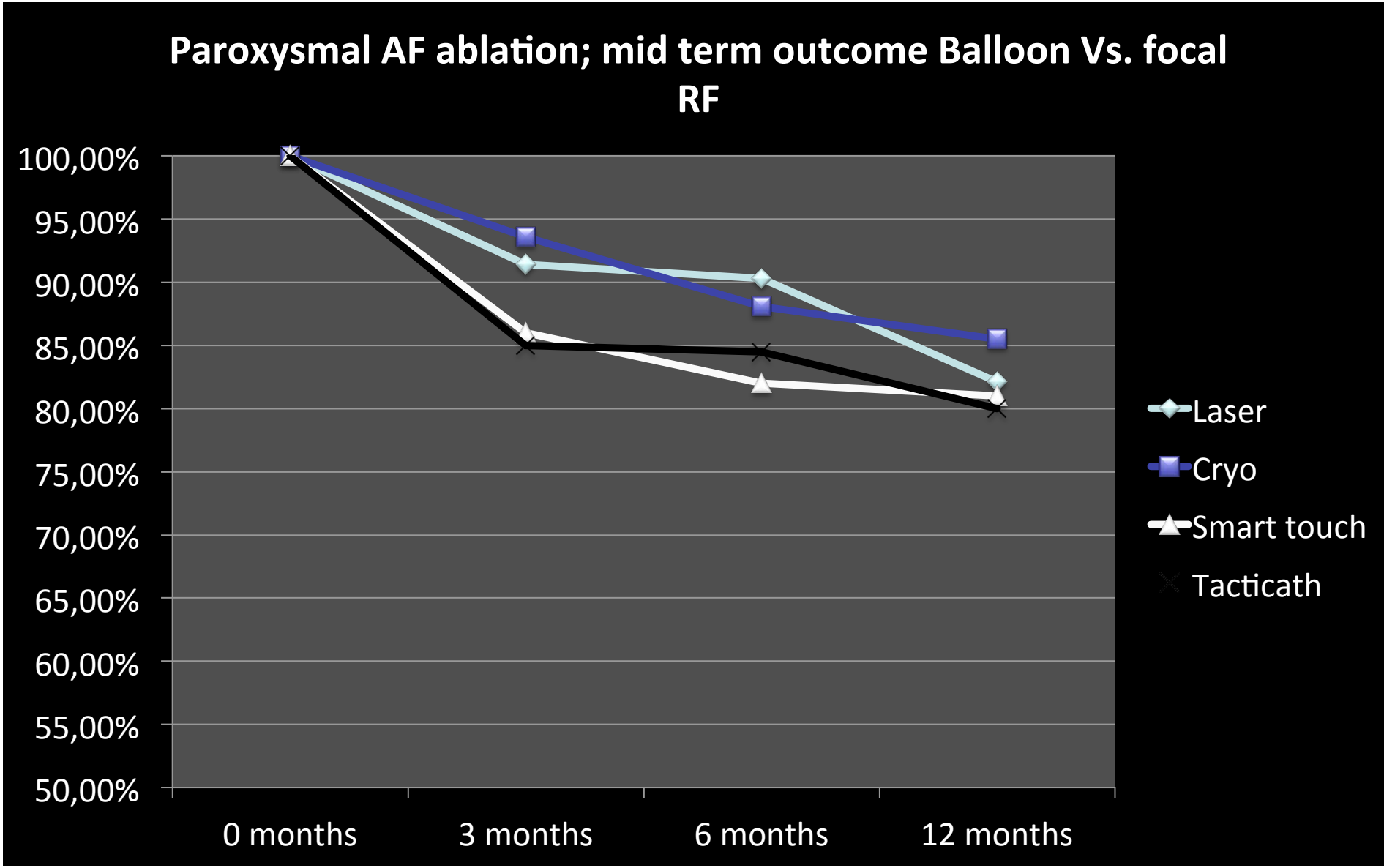


Fig. 2 Trend of ECI features for each of the four veins. *Asterisk* indicates a statistically significant difference

The main findings of our work is both, the evidence, in vivo, that ECI is a marker of tissue characteristics and, the identification of a cut-ff in ECI decrease able to predict the formation of a transmural and stable atrial tissue lesion. Thus, ECI monitoring during RF delivery may provide the clinician with valuable feedback regarding lesion depth. This may increase the efficacy and safety of AF catheter ablation procedures.

Dello Russo A, Tondo C, Natale A, JCE 2014

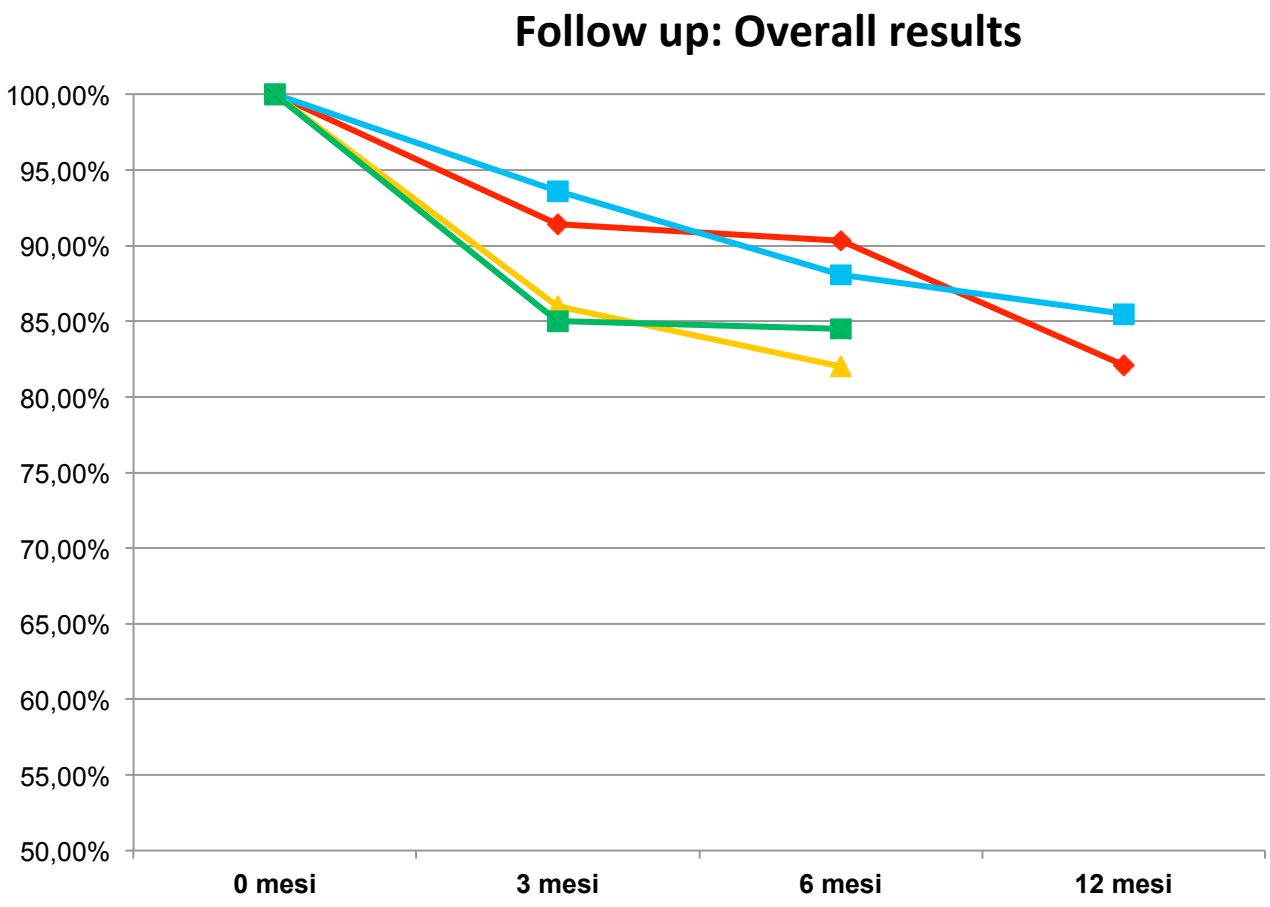

Paroxysmal AF ablation; mid term outcome Balloon Vs. focal RF
100,00%
95,00%
90,00%
85,00%
80,00%
75,00%
70,00%
65,00%
60,00%
55,00%
50,00%
0 months
3 months
6 months
12 months
Laser
Cryo
Smart touch
Tacticath

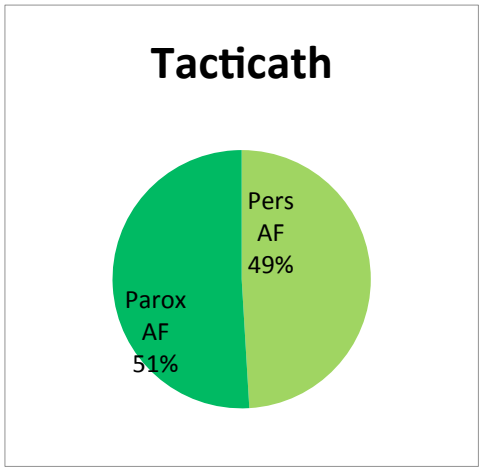
Conclusive Remarks

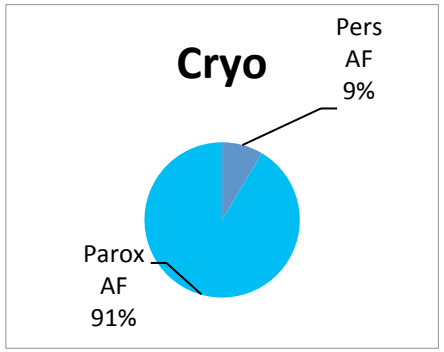
Will new technologies improve ablation of AF?

- $2^{nd}/3^{rd}$ generations CB provide high rate of acute PVI and offer a promising success rate at the mid-term follow up
- Visually-guided Laser ablation is equally effective for acute PVI and maintenance of sinus rhythm at mid-term follow up
- Loop-shaped ablation catheters are very effective and, still under investigation (N-Marq). They require technical improvement to ensure a high safety profile
- Sensing-force technology is the most critical advancement employed in conventional RF approach and it might play a critical role for durable PVI over the follow up

Ablation Technologies for Atrial Fibrillation Ablation







Personal Data