



October 16 - 18
14th EDITION 2015

Phased RF and Duty Cycled technologies for AF ablation: how could be more simple?



Giampiero Maglia, MD
Catanzaro



October 16 - 18
14th EDITION **2015**

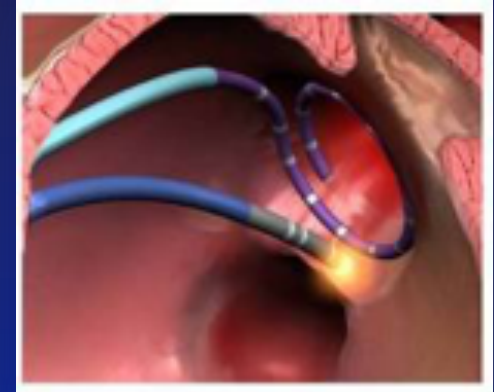
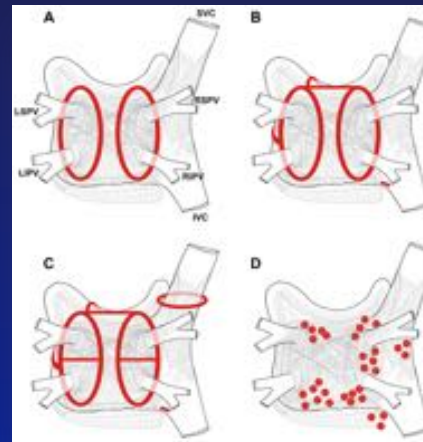


**NO CONFLICT OF
INTEREST TO
DECLARE**

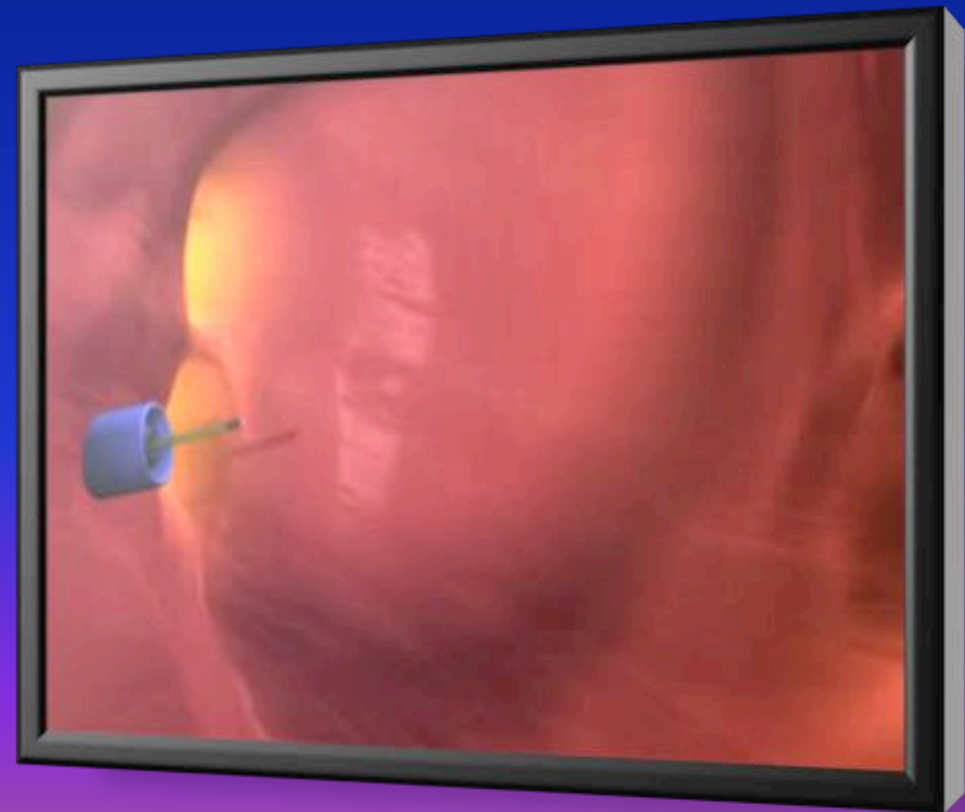
Why Simple?

1. The Approach
2. The Energy
3. The catheter
4. The User interface

The Approach



- **PVI as the cornerstone of AF ablation**
- **How do we achieve and validate?**
- **«One Shot» approach with the purpose to make the procedure safe, effective and predictable**



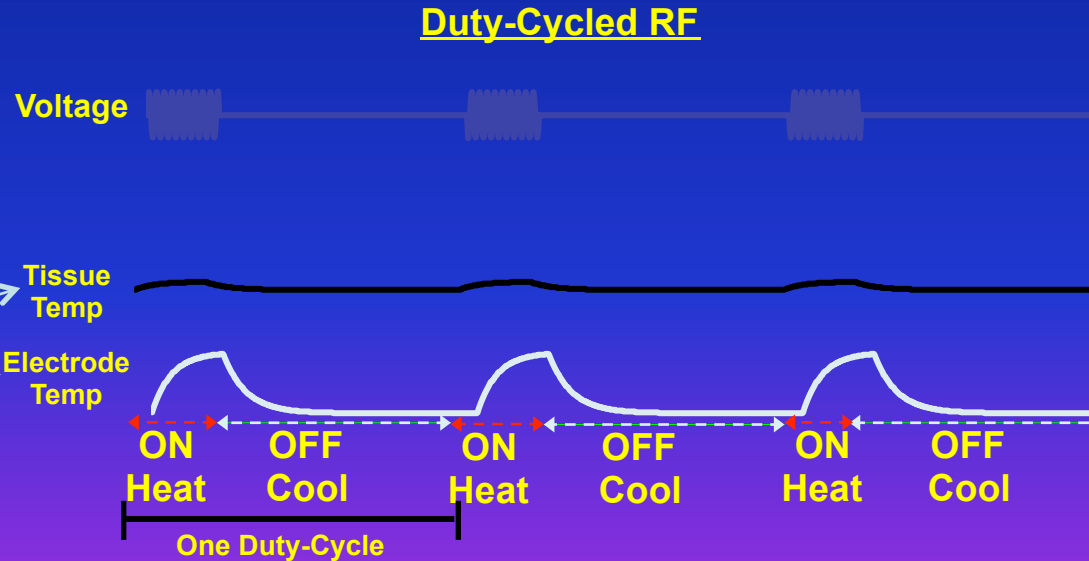
The Energy Duty-Cycled vs. Conventional RF

Duty-Cycling Allows Sufficient Electrode Cooling and Accurate Temperature Measurement

In conventional RF, power is continuously delivered and saline cooling is required to deliver enough power

In duty-cycled RF, power is turned on and off many times a second, allowing electrodes to cool in the off-cycle

During the 'off' period, tissue temperature remains close to target² while back of electrodes cool

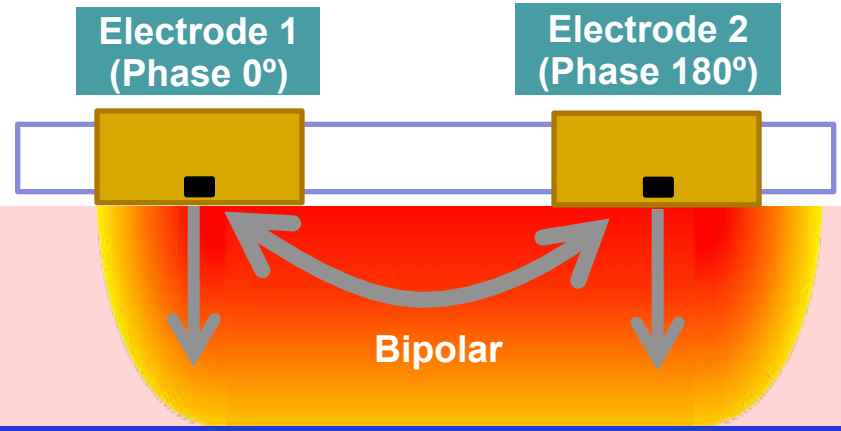
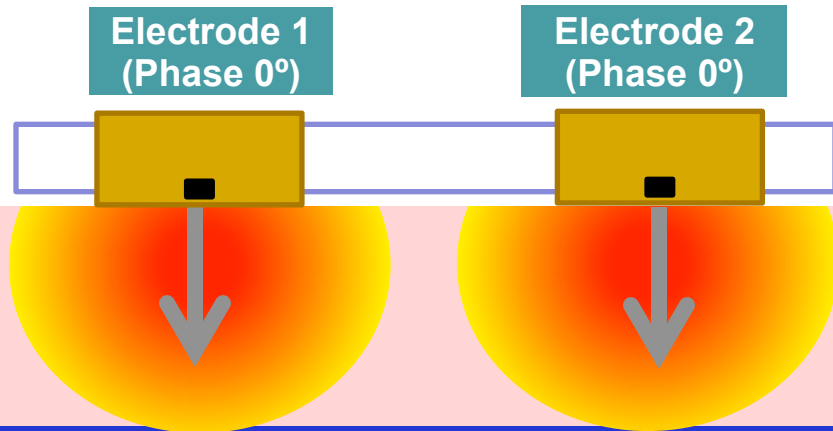


Phasing for Lesion Contiguity and Depth

Phasing Delivers Simultaneous and Controlled Unipolar Energy for Lesion Depth & Bipolar Energy for Lesion Length

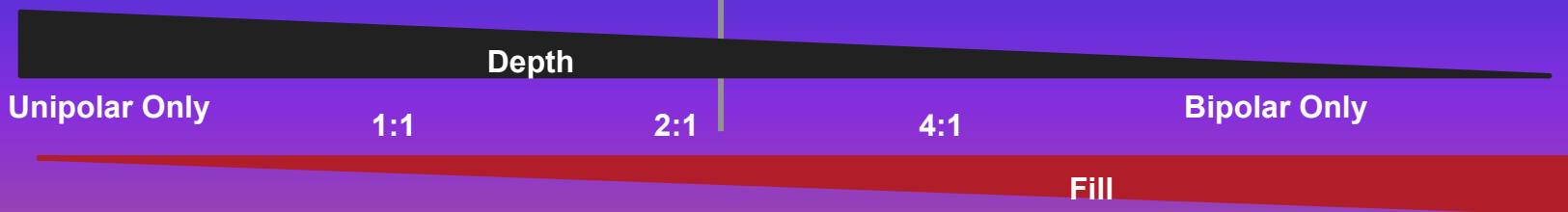
Electrode 1 and 2 are in Phase

Electrode 1 and 2 are Out of Phase



Unipolar Only

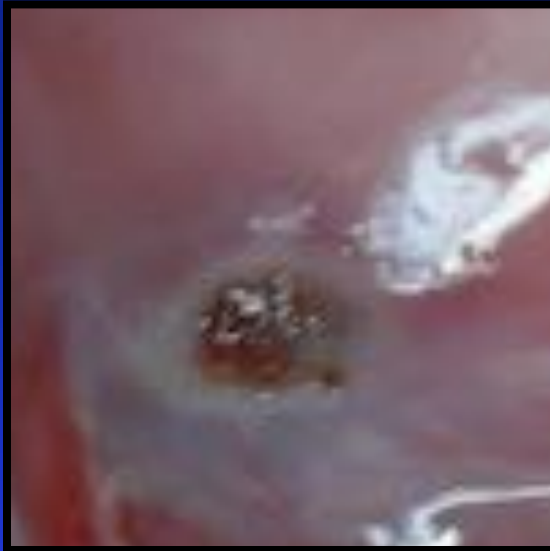
Unipolar and Bipolar



In Vivo Ablation Lesions

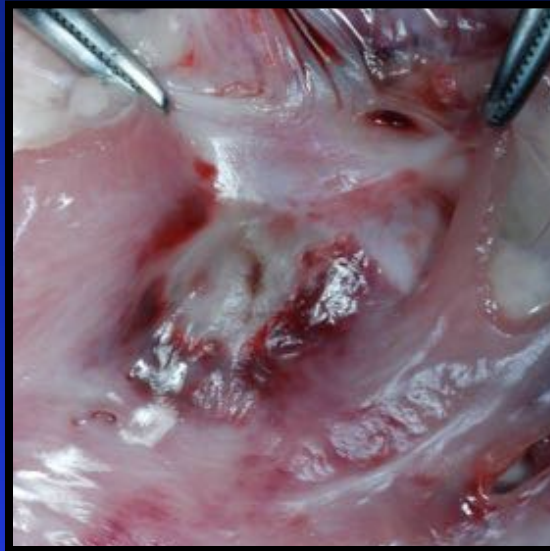
Conventional, Irrigated and Duty-Cycled Phased RF

Conventional RF



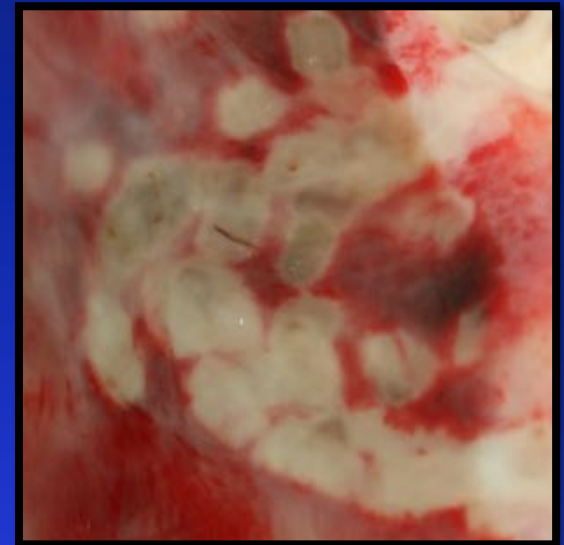
Thrombus over ablated area*

Irrigated RF



Focal ablation with minimal charring/coagulation**

Duty-Cycled, Phased RF



No endocardial disruption or adherent coagulum, smooth, well demarcated lesions***

*Study ID S2212 – Pathology report, data on file

**Study ID S2964.008 – Pathology report, data on file

*** Haines et al. Evaluation of gold/platinum electrode multipolar phased RF ablations in a swine model *In Vivo*: Microembolus production and energy delivery performance. ESC Poster 2012

The Catheter: PVAC GOLD

- **9 Gold Electrodes**
- **Map, ablate and validate with 1 Catheter**
- **Excellent temperature control**
- **Array tilted by 20° to ensure good contact with tissue**



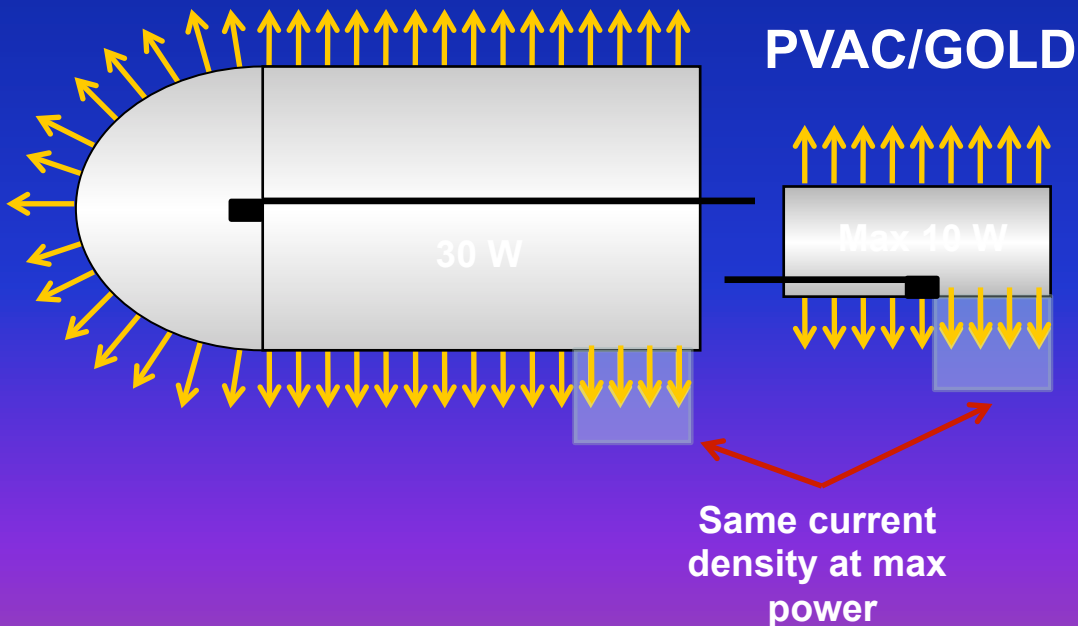
- **Bidirectional Deflection (180°)**

- **“Over The Wire” technology, to easily manuvre the catheter and keep the catheter stable, during ablation**

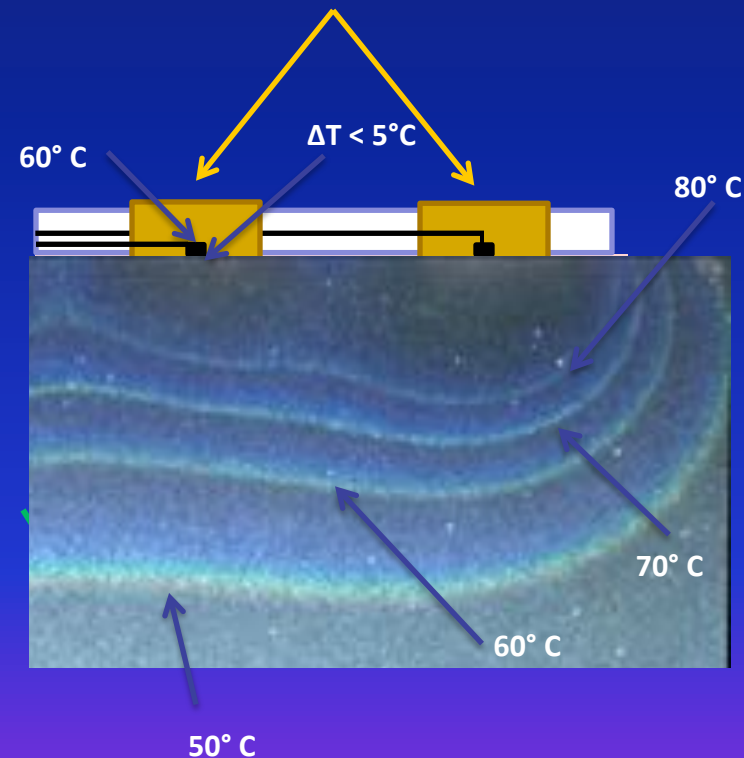
Accurate Temperature Control

- Thermocouple placed at electrode-tissue interface to improve accuracy of temperature measurement
- Temperature control and lack of irrigation permit tight temperature control, eliminating opportunity for steam pops
- Standard 4mm tip has large metal mass with embedded thermocouple distant from surface

Standard 4mm Tip

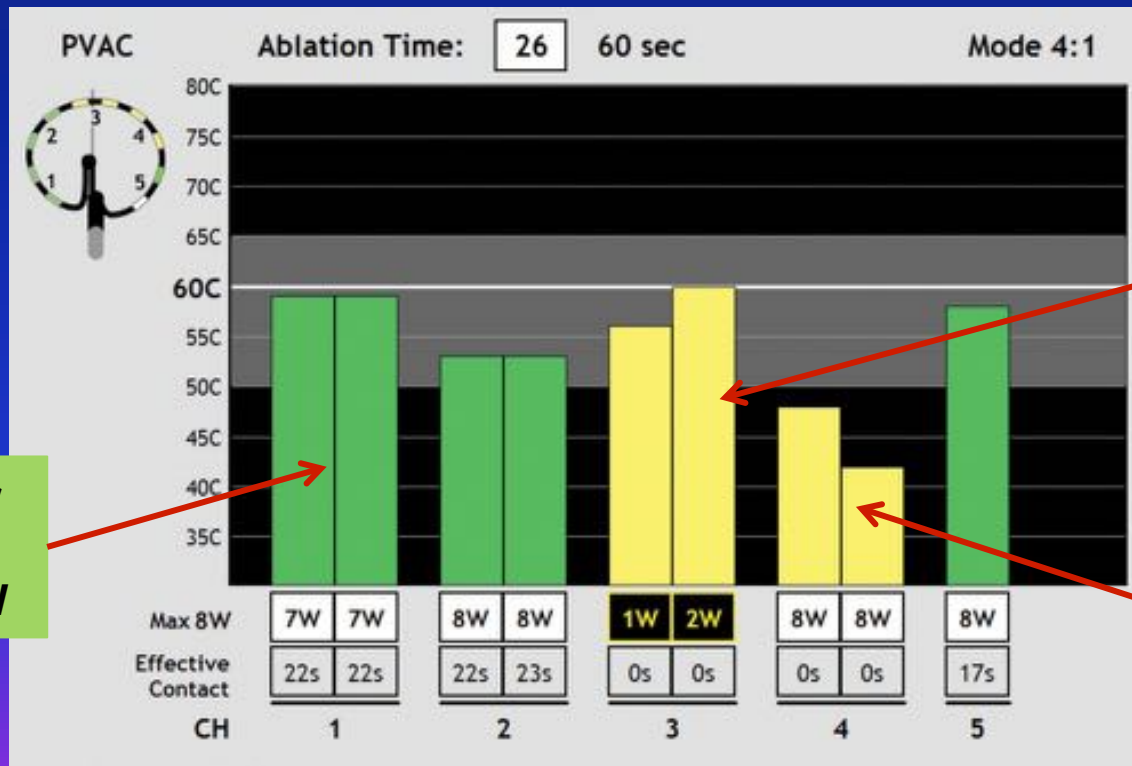


Thermocouple at electrode/tissue interface



New User Interface

- *De Greef et al* have demonstrated that good power and good temperature produces effective lesions¹
- New ContactIQ user interface highlights electrodes with both good power and good temperature

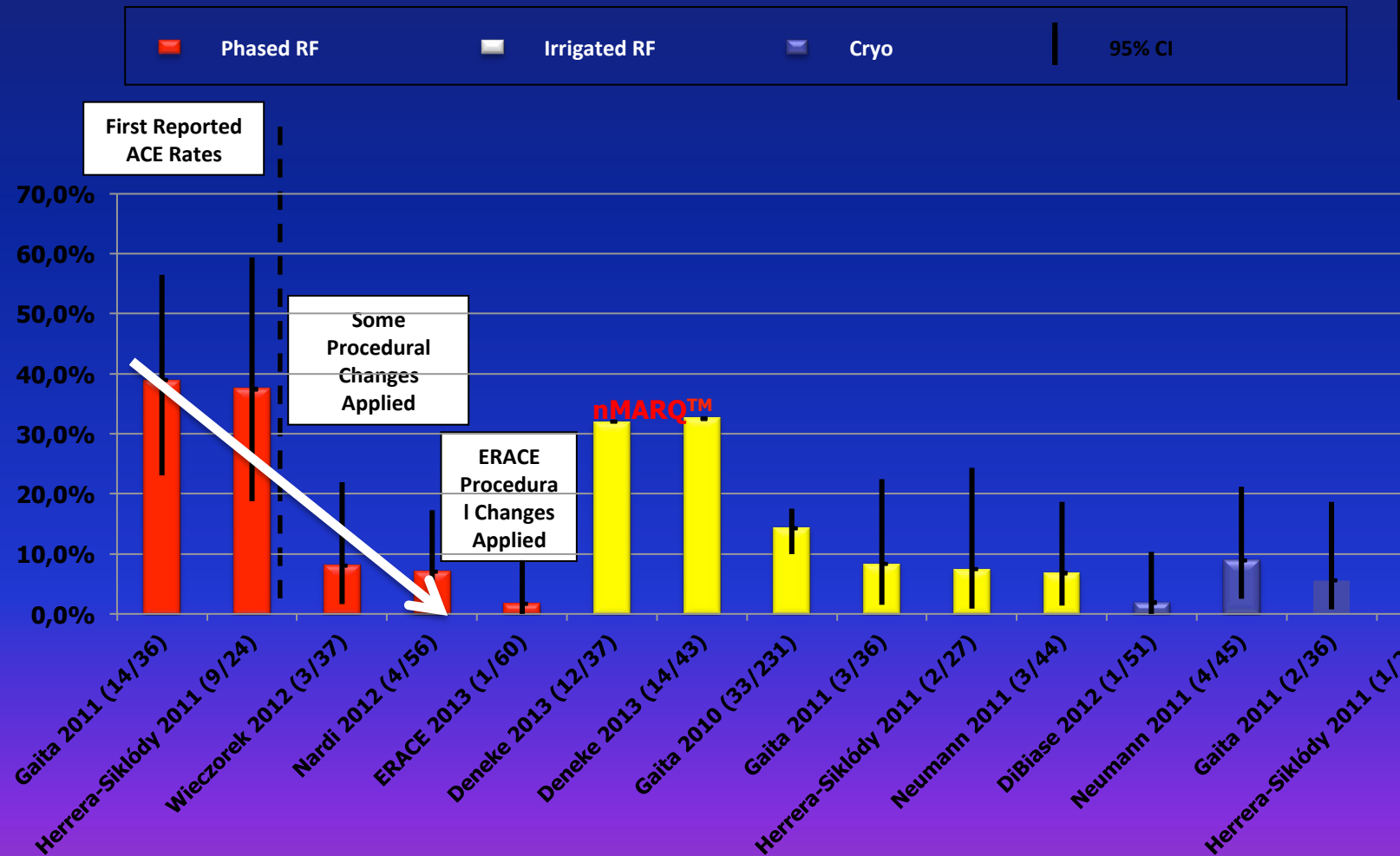
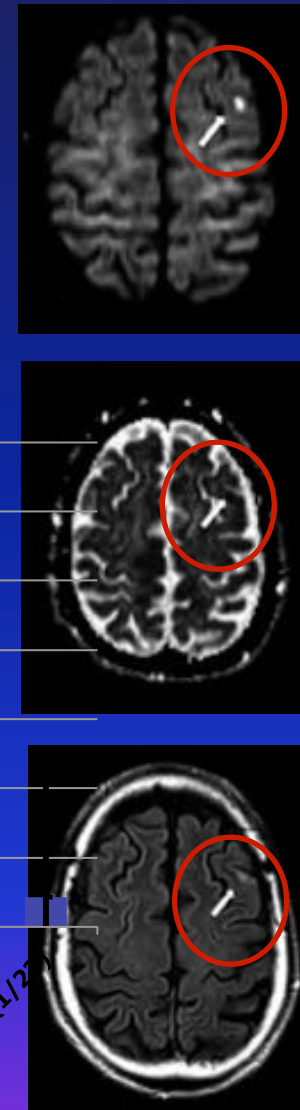


Green Bar
50 - 65°C +
Power ≥ 3W

**Yellow Bar/
Black Box**
50 - 65°C +
Power < 3W

**Yellow
Bar/ White
Box**
< 50°C

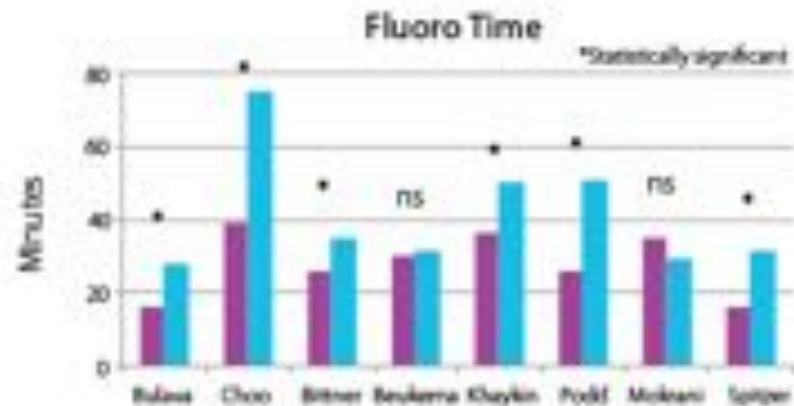
Best Practices lead to reduced incidence of ACE



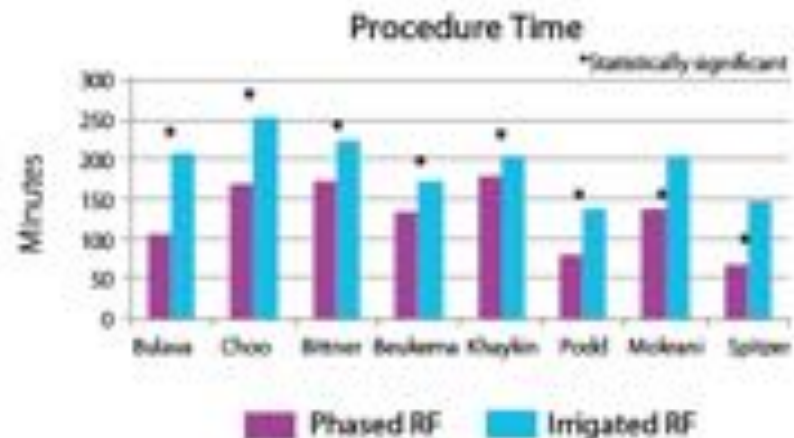
Caution: Clinical results across studies/protocols may not be comparable.
 Studies included used 1.5T MRI scanner and used Gaita/Herrera-Siklódy definition

Phased RF Demonstrates Reduced Fluoroscopic Exposure and Shorter Procedure Times vs Irrigated RF with 3-D Mapping

- Phased RF repeatedly demonstrates statistically significant reductions in fluoroscopic time^{18-20,22,23,25}



- Phased RF procedures reduced lab occupancy time¹⁸⁻²⁵
- Statistically significant procedure time reductions can be achieved by both new and experienced RF ablators^{19,20}

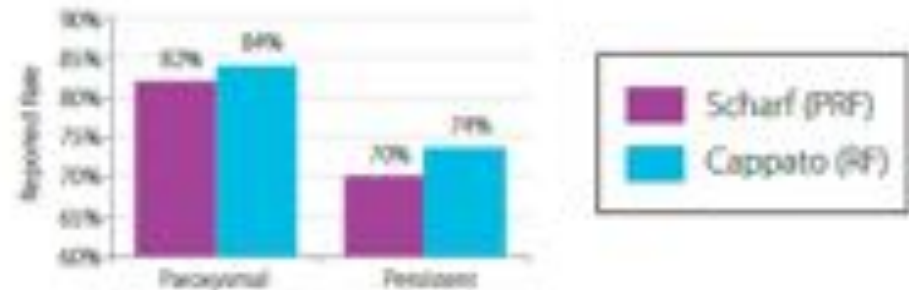


European Survey on Efficacy on Duty-Cycled Radiofrequency Ablation for Atrial Fibrillation

The largest Phased RF patient cohort to date (2,128 paroxysmal and 620 persistent patients)

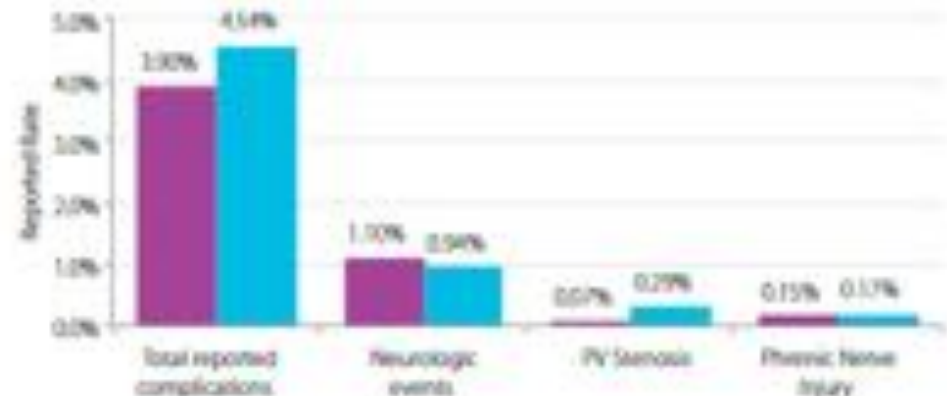
Effectiveness Results

- Similar one year effectiveness as compared to conventional RF²
- Short learning curve: efficacy was unrelated to center experience or case load



Safety Profile

- As compared to conventional RF²
 - Similar overall complication rate
 - Similar neurologic event rate
 - Similar PV stenosis rate
- Short learning curve: complications are unrelated to center experience or case load



*20 centers in 7 countries

International Peer Reviewed Data Demonstrates High Effectiveness with Low Rate of Complications

Author(s)	N	Disease	Outcome	Follow-Up Method	Fluoro Time (min)	Procedural Time (min)	Complications
Teig/Scharf ¹ Int J Journal of Card ES (12)	143	PAF	82%	8.5 ± 6.5 months	29 ± 13	128 ± 38	2 (0)
	66	CAF	79%	11.5 ± 8.5 months	46 ± 16	171 ± 39	
Nand ² HRS 2012, P03-132	139	CAF	54.7%	22.5 ± 5 months 4d Holter	24 ± 3	80 ± 32	3 (0)
Mulder ³ Europace (02/12)	120	PAF	55% 12 months 49% 24 months	12 months, 24 months 7d/3d Holter	NR	86 ± 26	5 (0)
Maglis ⁴ Circulation, 2011	200	PAF	75.1%	24 months 4d Holter	19 ± 3	52 ± 7	2 (0)
Tang ⁵ (2012)	20	PAF/CAF	70%	7 months	20.1 ± 6.3	87.5 ± 12.1	0
Mulder/Boersma ⁶ Europace (12/11)	89	CAF	50%	12 months 7d Holter	21 ± 10	111 ± 32	3 (0)
Zou ⁷ (2011)	105	72 PAF 33 CAF	86%	15.8 ± 6.4 months	38 ± 4	141 ± 38	1 (0)
Boersma ⁸ Europace (04/10)	102	90 PAF 12 CAF	60.8%	12 months 7d Holter	32 ± 11	139 ± 38	0
Wiczorek ⁹ JCI (10/08)	88	PAF	79%	12 months 7d Holter	21 ± 13	125 ± 28	0
Dereke ¹⁰ Hospital Chronicles ES (10)	106	106 PAF	65%	4 months 7d Holter	20 ± 8	100 ± 26	0
	46	46 PAF	47%				
Spitzer ¹¹ (2010)	81	PAF/CAF	78%	6 months	19 ± 7	83 ± 18	1 (0)
Duytschaever ¹² (2010)	27	PAF	74%	3 months	NR	176 ± 25	0
Mulder/Boersma ¹³ Europace (09)	118	PAF	76%	12 months 7d Holter	23 ± 14	86 ± 28	0
Friedlander ¹⁴ JCI (10/08)	21	17 PAF 4 CAF	86%	4 months 3d Holter	32 ± 10	121 ± 19	0
Scharf ¹⁵ JACC (04/08)	50	CAF	66%	20 months 7d Holter	55 ± 35	155 ± 40	1 (0)

- a) 1 TIA, 1 Afib abula, 1 tamponade
 - b) 2 TIA^a
 - c) 1 TIA, 1 ST elevation, 1 pericarditis
 - d) 2 Afib abula, 1 pseudoaneurysm
 - e) 2 groin haematoma^a
 - f) 1 femoral artery aneurysm
 - g) 1 stroke, 1 TIA, 1 PV stenosis
 - h) 1 ACl, 1 TIA, 1 MI
- ^a Data overlaps between Scharf et al. 2008 and Scharf/Teig, et al. 2010

Gold AF Registry

Design



Design:

- Postmarket release (PMR), multi-national, multi-center, prospective, observational study

Purpose:

- The purpose of the registry is to describe the use of Phased RF system in a standard clinical care practice and to evaluate its performance.

Scope:

- 1050 patients in approximately 50 centers. Centers are not preselected by experience criteria with Phased RFA.

Duration:

- Enrollment period is expected to last two years as of first enrollment. Each patients will be FU one year.

Gold AF Registry

Objectives



Main objectives:

- Estimate Phased RF ablation outcome through AF recurrence

Additional:

- Estimate Phased RF procedure safety through collecting procedure and/or system related adverse events

Ancillary objectives

- Estimate the acute procedural success rate
- Estimate procedural efficiency
- Describe peri-procedural anticoagulation strategy
- Describe patient population treated
- Rate and dynamic of QoL (AFEQT Questionnaire)

Gold AF Registry

Regional distribution



Countries	Number of sites
Germany	13
Netherlands	5
Canada	3
UK	6
Israel	4
Poland	4
France	4
Belgium	3
Italy	6
Spain	3
Switzerland	2
Total: 11	53

Steering Committee

13 Steering Committee

The Steering Committee (SC) will be an advisory body to the GOLD AF registry. SC members are responsible for collaboration and guidance on study goals, design, study center communications, training materials and other activities based on expertise or as agreed upon.

The study's SC will be comprised of non-Medtronic physicians listed below:

Coordinating investigator:	Dr. L Boersma, Nieuwegein , Netherlands
Co-coordinating investigator:	Dr. M Hocini, Bordeaux, France
Steering committee members:	Dr. F Arribas, Madrid, Spain
	Dr. L Dekker, Eindhoven, Netherlands
	Dr. M Duytschaever, Bruges, Belgium
	Prof. A Götte, Paderborn, Germany
	Dr. F Halimi, Le Chesnay, France
	Dr. G Maglia, Catanzaro , Italy

Ablation of paroxysmal and persistent atrial fibrillation with multielectrode phased radiofrequency duty-cycled catheters: long-term results from a large cohort of patients

Stefano Nardi^a, Luigi Argenziano^a, Riccardo Cappato^b, Giuseppe de Martino^c, Cristina Esposito^d, Mariano Scaglione^a, Francesco Borrello^e and Giampiero Maglia^e

Background Catheter ablation is a widely used approach to treat patients with drug refractory paroxysmal atrial fibrillation (PAF) and persistent atrial fibrillation (CAF). The aim of this analysis was to evaluate the long-term safety and efficacy of the multi-electrode/phased RF/duty-cycled ablation catheters in the treatment of both PAF and CAF in a large cohort of patients.

Methods and results From July 2008 to February 2010, 429 consecutive drug refractory symptomatic patients (mean age 60 ± 12 years old, 58% men, 68% PAF, 32% CAF) were treated. Seventy-five patients had two procedures resulting in a total of 504 procedures (procedure mean time: 62 ± 15 min). Following ablation, 4-day continuous Holter monitoring was done every 3 months. Recurrence was defined as any atrial tachyarrhythmia more than 30 s. 97.4% of patients were off antiarrhythmic drugs at 3 months. During a mean follow-up of 22 ± 5 months, freedom from AF recurrence was 68.5% (95% CI: 63.8–72.6) and higher for PAF than CAF patients. The risk of AF recurrence in PAF patients increased in presence of hypertension, dyslipidemia, large left atrial diameter (LAD) and low ejection fraction. For CAF patients, the risk of AF recurrence increased

with larger LAD and lower ejection fraction. Complications that resolved prior to discharge were observed in nine patients (2.1%) with no strokes/transient ischemic attacks (TIAs).

Conclusion The ablation of symptomatic PAF and CAF with multielectrode phased radiofrequency/duty-cycled ablation catheters shows long-term safety and effectiveness with relatively short procedure times.

J Cardiovasc Med 2013, 14:000–000

Keywords: atrial fibrillation, catheter ablation, duty-cycled radiofrequency, pulmonary vein isolation

^aPireta Grande Hospital, Castel Volturno, ^bIRCCS Istituto Policlinico San Donato, Milan, ^cCristo Re Hospital, Rome, ^dSanta Maria Hospital, Terni and ^ePugliese-Ciaccio Hospital, Catanzaro, Italy

Correspondence to: Stefano Nardi, MD, UOC di Aritmologia ed Elettrofisiologia cardiaca, Pireta Grande, Castel Volturno, Via Domitiana km 30, 81030 Castel Volturno, Caserta, Italy
Tel: +39 0823 851007; fax: +39 0823 851007; e-mail: nardi.stefano@libero.it

Funding and Disclosures: There were no funding for this analysis since data were gathered by the investigators. Stefano Nardi reports receiving consulting and proctoring fee from Medtronic Inc. No other author reported disclosures.

Received 29 October 2012 Revised 30 January 2013
Accepted 17 February 2013

Ablation of paroxysmal and persistent atrial fibrillation with multielectrode phased radiofrequency duty-cycled catheters: long-term results from a large cohort of patients

Stefano Nardi^a, Luigi Argenziano^a, Riccardo Cappato^b, Giuseppe de Martino^c, Cristina Esposito^d, Mariano Scaglione^a, Francesco Borrello^e and Giampiero Maglia^e

Table 1 Characteristics of 429 patients who were treated with phased radiofrequency technology

	Overall N = 429	Paroxysmal N = 290	Persistent N = 139	P-value	No REDO N = 376	REDO N = 53	P-value
Age	60 (12)	59 (12)	62 (11)	0.016	60 (11)	58 (13)	0.288
Sex (male)	248 (57.8%)	162 (55.9%)	86 (61.9%)	0.238	217 (57.7%)	31 (58.5%)	0.915
Type of AF							0.068
PAF	290 (67.6%)				260 (69.2%)	30 (56.6%)	
CAF	139 (32.4%)				116 (30.8%)	23 (43.4%)	
Number of AADs	2.6 (0.6)	2.6 (0.6)	2.6 (0.6)	0.143			
Comorbidity	206 (47.8%)	112 (38.6%)	93 (66.9%)	< 0.0001			
CAD	65 (15.2%)	30 (10.3%)	35 (25.2%)	< 0.0001	37 (9.8%)	28 (52.8%)	< 0.0001
Hypertension	166 (38.7%)	94 (32.4%)	72 (51.8%)	< 0.0001	122 (32.5%)	44 (83.0%)	< 0.0001
Dyslipidemia	115 (26.8%)	59 (20.3%)	56 (40.3%)	< 0.0001	77 (20.5%)	38 (71.7%)	< 0.0001
Diabetes	42 (9.8%)	20 (6.9%)	22 (15.8%)	0.004	25 (6.7%)	17 (32.1%)	< 0.0001
Number of comorbidities	1.9 (1.0)	1.8 (0.9)	2.0 (1.0)	0.196			
Anticoagulation therapy	358 (83.4%)	220 (75.9%)	138 (99.3%)	< 0.0001			
Left atrium diameter (mm)	4.3 (0.4)	4.2 (0.2)	4.7 (0.4)	< 0.0001	4.3 (0.3)	4.7 (0.4)	< 0.0001
Left ventricle ejection fraction (%)	57 (7)	58 (7)	55 (7)	< 0.0001	58 (7)	48 (3)	< 0.0001
Pts (%) with AADs at discharge	379 (88.3%)	245 (84.5%)	134 (97.8%)	< 0.0001	333 (89.0%)	46 (86.8%)	0.628
Pts with AADs at 3 months	11 (2.6%)	5 (1.7%)	6 (4.3%)	0.187	7 (1.9%)	4 (7.6%)	0.036

Data are expressed as mean (SD) or as absolute (relative). AADs, antiarrhythmic drugs; AF, atrial fibrillation; CAD, coronary artery disease. CAF, persistent AF; PAF, paroxysmal AF.

Ablation of paroxysmal and persistent atrial fibrillation with multielectrode phased radiofrequency duty-cycled catheters: long-term results from a large cohort of patients

Stefano Nardi^a, Luigi Argenziano^a, Riccardo Cappato^b, Giuseppe de Martino^c, Cristina Esposito^d, Mariano Scaglione^a, Francesco Borrello^e and Giampiero Maglia^e

Table 2 Procedural and safety outcome data for the 504 procedures

	Overall N = 504	Paroxysmal N = 323	Persistent N = 181	P-value
Total procedure time (min)	62 ± 15	52 ± 7	80 ± 8	<0.0001
Fluoroscopy time (min)	21 ± 4	19 ± 3	24 ± 3	<0.0001
Pts with MASC	155 (30.8%)	-	155 (85.6%)	-
Pts with MAAC	174 (34.5%)	-	174 (96.1%)	-
LSPV (#ablations/vein)	5.5 ± 1.2	5.6 ± 1.1	5.3 ± 1.4	0.01
LIPV (#ablations/vein)	5.5 ± 1.4	5.7 ± 1.4	5.2 ± 1.4	<0.001
RSPV (#ablations/vein)	5.5 ± 1.4	5.6 ± 1.3	5.4 ± 1.5	0.182
RIPV (#ablations/vein)	5.3 ± 1.4	5.4 ± 1.3	5.2 ± 1.4	0.045
Total (#ablations/vein)	21.8 ± 4.7	22.3 ± 4.5	21.0 ± 4.9	0.002
Procedural complication rate	9 (1.8%)	2 (0.6%)	7 (3.9%)	0.0124

Data are expressed as mean (SD) or as absolute (relative). LIPV, left inferior pulmonary vein; LSPV, left superior pulmonary vein; MAAC, multi-array ablation catheter; MASC, indicates multi-array septal catheter; RIPV, right inferior pulmonary vein; RSPV, right superior pulmonary vein.

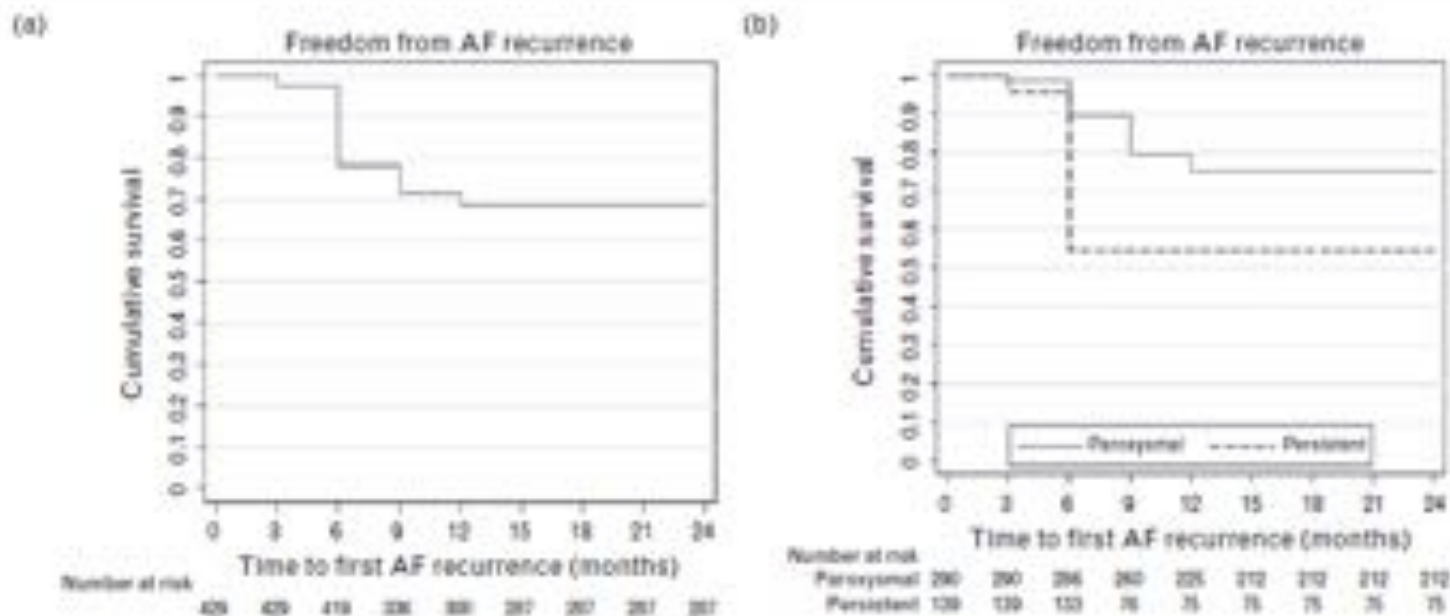
Ablation of paroxysmal and persistent atrial fibrillation with multielectrode phased radiofrequency duty-cycled catheters: long-term results from a large cohort of patients

Stefano Nardi^a, Luigi Argenziano^a, Riccardo Cappato^b, Giuseppe de Martino^c, Cristina Esposito^d, Mariano Scaglione^a, Francesco Borrello^e and Giampiero Maglia^e

During a mean follow-up of 25 months, 135 patients (31.5%) had an AF recurrence.

The 2-year freedom from AF recurrence rate was for PAF 75.1% and for CAF 54.7%

Fig. 2



Kaplan-Meier of freedom from atrial fibrillation (AF) recurrence for the overall population (a) and for patients with paroxysmal and permanent AF (b). Note that time to first AF recurrence is measured in all patients from their first AF ablation procedure.

Ablation of paroxysmal and persistent atrial fibrillation with multielectrode phased radiofrequency duty-cycled catheters: long-term results from a large cohort of patients

Stefano Nardi^a, Luigi Argenziano^a, Riccardo Cappato^b, Giuseppe de Martino^c, Cristina Esposito^d, Mariano Scaglione^a, Francesco Borrello^e and Giampiero Maglia^e

Table 3 Univariate and multivariate predictors of atrial fibrillation recurrence

Covariate	Patients with persistent atrial fibrillation			HR	Multivariate	
	HR	95%CI	P-value		95%CI	P-value
Age >65 years	0.7	0.4-1.2	0.162			
Male	1.2	0.7-2.1	0.416			
Coronary artery disease	3.6	2.2-5.9	<0.0001	1.0	0.5-1.9	0.950
Hypertension	6.7	3.2-14.1	<0.0001	2.1	0.9-4.6	0.070
Dyslipidemia	4.3	2.5-7.5	<0.0001	1.8	0.9-3.7	0.099
Diabetes	2.0	1.1-3.4	0.017	1.4	0.8-2.6	0.215
Number of comorbidities	1.9	1.6-2.3	<0.0001			
Left atrium diameter (mm)	1.2	1.2-1.3	<0.0001	1.1	1.0-1.2	0.003
Left ventricle ejection fraction (%)	0.9	0.8-0.9	<0.0001	0.9	0.8-0.9	0.003

Ablation of paroxysmal and persistent atrial fibrillation with multielectrode phased radiofrequency duty-cycled catheters: long-term results from a large cohort of patients

Stefano Nardi^a, Luigi Argenziano^a, Riccardo Cappato^b, Giuseppe de Martino^c, Cristina Esposito^d, Mariano Scaglione^a, Francesco Borrello^e and Giampiero Maglia^e

In conclusion, our experience on a large cohort of patients treated with multielectrode phased radiofrequency/duty-cycled ablation system, shows that this technology is safe and effective, both in terms of acute and long-term outcomes. The ablation approach is simple and allows for short procedural and fluoroscopy exposure time. There