

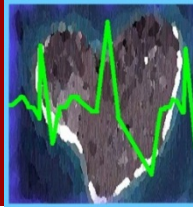
# Micro eventi tromboembolici: quale impatto clinico e quali soluzioni tecnologiche possono mitigarli ?

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# Worldwide Survey 2010 vs 2005



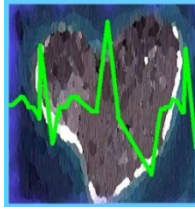
➤ 521 centers from 24 countries in 4 continents.

➤ Complete interviews were collected from 182 centers, of which 85 reported to have performed 20825 catheter ablation procedures on 16309 patients with AF between 2003 and 2006.

➤ All centers included paroxysmal AF, 85.9% also included persistent and 47.1% also included long-lasting AF. Carto-guided left atrial circumferential ablation (48.2% of patients) and Lasso-guided ostial electric disconnection (27.4%) were the most commonly used techniques.

	Previous Survey	Current Survey
Period Investigated	1995–2002	2003–2006
No. of centers enrolled	90	85
No. of patients	8745	16 309
No. of patients per center	97	192
No. procedures	12 830	20 825
No. procedures per patient	1.5	1.3
Male, %	63.8	60.8
Lower and upper age limit for entry	18–82	15–90
Proportion of centers (%) performing ablation of		
Paroxysmal AF	100	100
Persistent AF	53.4	85.9
Long-lasting AF	20	47.1
Success rate, %, median		
Free of AADs	52.0	70.0
With AADs	23.5	10.0
Overall	75.5	80.0
Proportion of centers (%) using as exclusion		
Left atrial size upper limit	46.3	31.8
Prior heart surgery	65.1	23.5
Lower cut-off limit of LVEF	64.3	22.4
Overall complication rate, %	4.0	4.5
Iatrogenic flutter	3.9	8.6

# Incidence and Predictors of Periprocedural Cerebrovascular Accident in Patients Undergoing Catheter Ablation of Atrial Fibrillation

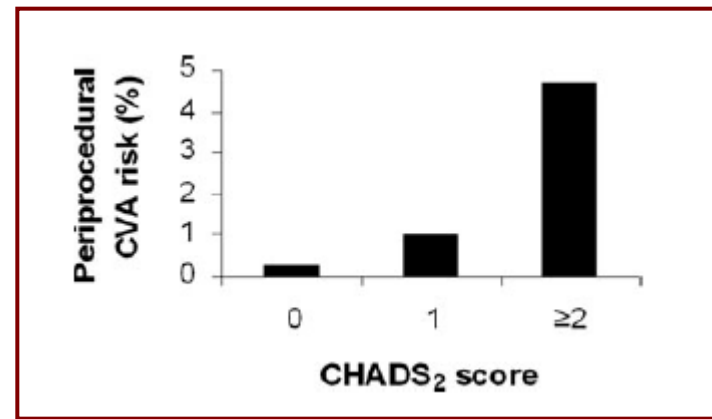


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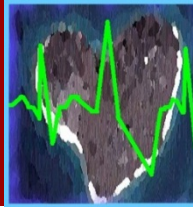
Univariate Analysis Comparing Cases with and without Periprocedural CVA

Variable	Stroke (n = 10)	Control (n = 711)	P
Female gender	1 (10)	166 (23)	0.47
Age (years)	62 ± 11	57 ± 11	0.22
History of AF (years)	6.3 ± 5.5	6.3 ± 5.7	0.99
Warfarin prior to ablation	8 (80)	672 (95)	0.11
Persistent AF	5 (50)	340 (48)	1.0
AF at time of procedure	7 (70)	326 (46)	0.71
History of prior AF ablation	1 (10)	145 (20)	0.70
LA diameter (cm)	4.8 ± 0.5	4.7 ± 0.7	0.54
LVEF (%)	55 ± 8	57 ± 9	0.45
History of CAD	4 (40)	75 (11)	0.02*
Prior CVA	4 (40)	39 (5)	<0.01*
CHADS <sub>2</sub> score = 0	1 (10)	366 (51)	<0.01*
CHADS <sub>2</sub> score = 1	2 (20)	204 (29)	0.73
CHADS <sub>2</sub> score ≥ 2	7 (70)	141 (20)	<0.001*
Procedure duration (min)	266 ± 53	257 ± 62	0.63
Duration in LA (min)	169 ± 36	167 ± 59	0.88
Ablation duration (min)	42 ± 18	41 ± 19	0.80
Irrigated tip catheter	6 (60)	316 (44)	0.35

Despite periprocedural anticoagulation and transesophageal echocardiography, we found a 1.4% incidence of periprocedural CVA in AF ablation patients. A CHADS<sub>2</sub> score ≥ 2 and a history of CVA are independent predictors of CVA after AF ablation. The CVA risk is low in patients with CHADS<sub>2</sub>



# Early heparinization decreases the incidence of left atrial thrombi



- ✓ All patients received intravenous heparin prior to catheter manipulation and ablation in the left atrium. **Heparin was administered initially as an intravenous bolus (2,500–5,000 units) followed by a continuous infusion (600–2,000 units per hour).**
- ✓ ACT was monitored at **15–30-min** intervals with a target ACT between 300 and 400 s.
- ✓ **preTS1 group:** heparin was administered following venous and arterial sheath placement but before the first transseptal puncture.
- ✓ **TS1-TS2 group:** heparin was administered following the first transseptal puncture (as documented by left atrial contrast bubbles noted on ICE, left atrial pressure tracing, or left atrial angiography).
- ✓ **postTS2 group:** intravenous heparin was administered only after completion of the second transseptal puncture.

When patients received heparin therapy either preTS1 or TS1-TS2, there was a significant decrease in the occurrence of ICE-detected left atrial thrombus compared with those who received heparin postTS2

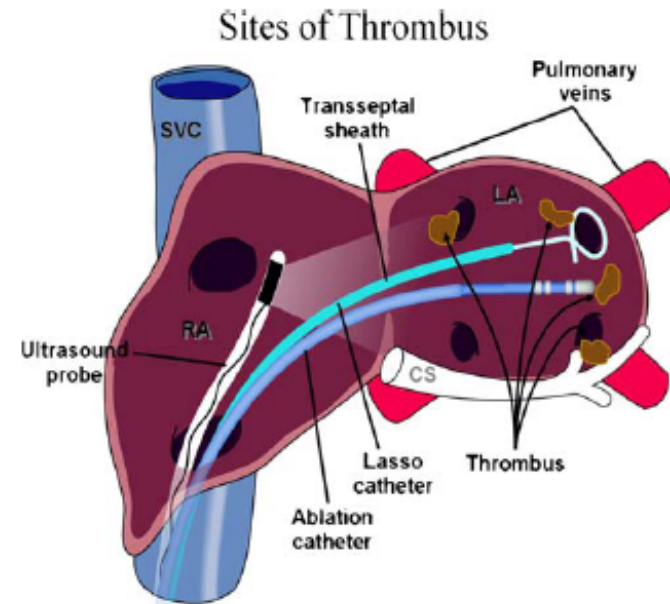
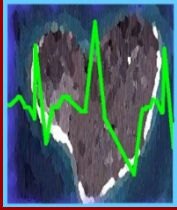


Fig. 4 The ultrasound probe placed in the right atrium in the region of the interatrial septum was used to visualize thrombus. Thrombus was detected at various locations including on the transseptal sheath-Lasso catheter, ablation catheter, or in the left atrium (see text for details)

Bruce et al. *J Interv Card Electrophysiol* (2008) 22:211-219

# Anticoagulant therapy during periprocedural AF ablation period



**Table 1. Patient Characteristics**

Characteristic	LMWH 1 mg/kg BID (n=105): Group 1	LMWH 0.5 mg/kg BID (n=100): Group 2	Warfarin (n=150): Group 3	P
Age, y	56±9.6	55.5±12.0	55.1±10.6	0.652
Female gender, %	21	20	25	0.477
LVEF, %	54.3±8	52.4±9.3	55.8±8	0.312
LA diameter, cm	4.4±0.9	4.5±0.8	4.4±0.7	0.481
Creatinine, mg/dL	1.0±0.1	1.0±0.1	1.0±0.2	0.6
INR	1.17±0.3	1.2±0.2	2.7±0.5	0.001
Maximum ACT, s	468	475	500	0.6
SEC, %	25	26	2	0.001

LVEF indicates left ventricular ejection fraction; LA, left atrium; ACT, activated clotting time; and SEC, spontaneous echocardiographic contrast.

**Table 2. Complications**

	Group 1 (n=105)	Group 2 (n=100)	Group 3 (n=150)	Exact P
Ischemic stroke, n	1	2	0	0.12
Pericardial effusion, n	1	2	1	0.69
Minor bleeding, n	23	19	8	<0.001
Major bleeding, n	9	0	0	<0.001

**Conclusions**—Continuation of warfarin throughout pulmonary vein ablation without administration of enoxaparin is safe and efficacious.

This strategy can be an alternative to bridging with enoxaparin or heparin in the periprocedural period.

Wazni, Natale et al.  
Circulation 2007;116:2531-2534.



# Radiofrequency Catheter Ablation of Atrial Fibrillation: A Cause of Silent Thromboembolism?

## Magnetic Resonance Imaging Assessment of Cerebral Thromboembolism in Patients Undergoing Ablation of Atrial Fibrillation

Fiorenzo Gaita, MD; Domenico Caponi, MD; Martina Pianelli, MD; Marco Scaglione, MD; Elisabetta Toso, MD; Federico Cesarani, MD; Carlo Boffano, MD; Giovanni Gandini, MD; Maria Consuelo Valentini, MD; Roberto De Ponti, MD; Franck Halimi, MD; Jean François Leclercq, MD

**Background**—Radiofrequency left atrial catheter ablation has become a routine procedure for treatment of atrial fibrillation. The aim of this study was to assess with preprocedural and postprocedural cerebral magnetic resonance imaging the thromboembolic risk, either silent or clinically manifest, in the context of atrial fibrillation ablation. The secondary end point was the identification of clinical or procedural parameters that correlate with cerebral embolism.

**Methods and Results**—A total of 232 consecutive patients with paroxysmal or persistent atrial fibrillation who were candidates for radiofrequency left atrial catheter ablation were included in the study. Pulmonary vein isolation or pulmonary vein isolation plus linear lesions plus atrial defragmentation with the use of irrigated-tip ablation catheters was performed. All of the patients underwent preprocedural and postablation cerebral magnetic resonance imaging. A periprocedural symptomatic cerebrovascular accident occurred in 1 patient (0.4%). Postprocedural cerebral magnetic resonance imaging was positive for new embolic lesions in 33 patients (14%). No clinical parameters such as age, hypertension, diabetes mellitus, previous history of stroke, type of atrial fibrillation, and preablation antithrombotic treatment showed significant correlation with ischemic cerebral embolism. Procedural parameters such as activated clotting time value and, in particular, electric or pharmacological cardioversion to sinus rhythm correlated with an increased incidence of cerebral embolism. Cardioversion was also associated with an increased risk of 2.75 (95% confidence interval, 1.29 to 5.89;  $P=0.009$ ).

**Conclusions**—Radiofrequency left atrial catheter ablation carries a low risk of symptomatic cerebral ischemia but is associated with a substantial risk of silent cerebral ischemia detected on magnetic resonance imaging. Independent risk factors for cerebral thromboembolism are the level of activated clotting time and, in particular, the electric or pharmacological cardioversion to sinus rhythm during the procedure. (*Circulation*. 2010;122:1667-1673.)

# ASCE Findings from Literature Review

- The observation of asymptomatic cerebral embolism without neurological deficit on MRI following invasive cardiac interventions has been referenced in the literature for over 30 years

Procedure	Studies (n) (Total # pts)	Average % of procedures with new lesions & without neuro symptoms (Range in various studies)
Cardiac Valve Replacement	1 (30)	47%
CABG	3 (80)	34% (26 - 45%)
Coronary Angiography	1 (48)	15%
Carotid Artery Stenting	2 (53)	30% (22 - 50%)
Carotid Thromboendarectomy	2 (73)	4%

# Asymptomatic Silent Cerebral Embolism

- ACE describes an acute ischemic change in the brain due to an embolus that does not result in clinical symptoms.
  - Embolism can be caused by a blood clot (thromboembolism), gas, tissue or fat.
- Acute emboli without neurological deficit is not new to cardiac procedures.



# Asymptomatic Silent Cerebral Embolism

- Si tratta di procedure routinariamente eseguite su larga scala senza che la comunità scientifica abbia mai dibattuto sul rischio di un deficit cognitivo post procedurale
- **Sulla base delle evidenze in letteratura Kruis nel "*The (Un)Importance of Cerebral Microemboli*" afferma che NON è possibile confermare un link causale tra Microemboli e Deficit Cognitivo Post Operatorio**

Kruis, et al.<sup>4</sup> reviewed the literature looking at the association between Cerebral Emboli and Cognitive Decline following Cardiac Surgery Procedures:

- The authors performed an independent review of 22 Cardiac Surgery studies from the past 3 decades. Fifteen studies used Trans-cranial Doppler (TCD) (n = 1,829 patients) and 7 used Diffusion Weighted-MRI (n = 379 patients)
- 66% of all studies reviewed showed no association between cerebral emboli and risk of cognitive decline while 34% of all studies did find an association
- The authors concluded that based on the review of published studies they could not confirm an association between microemboli and Post-Operative Cognitive Decline (POCD)

# Radiofrequency Catheter Ablation of Atrial Fibrillation: A Cause of Silent Thromboembolism?

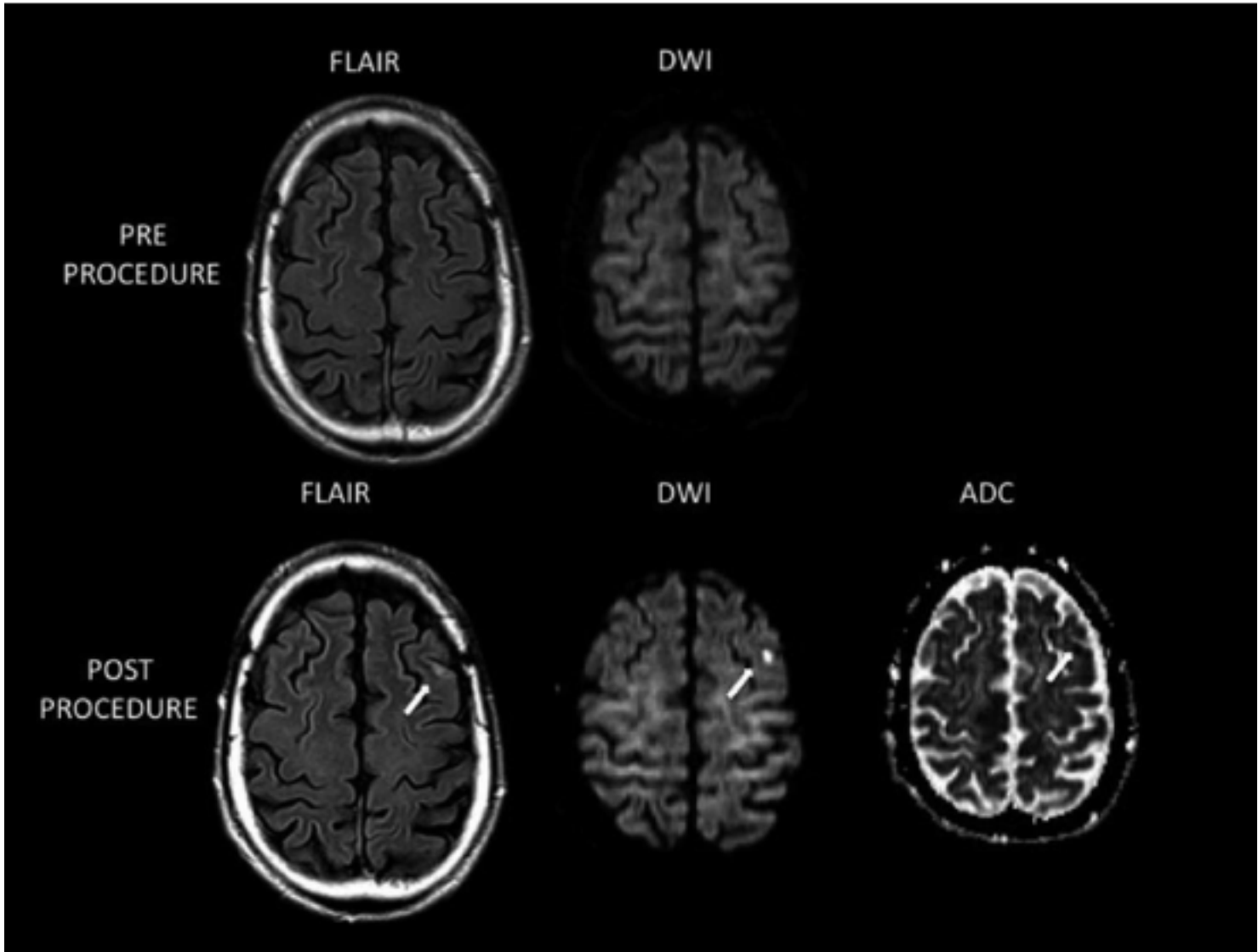
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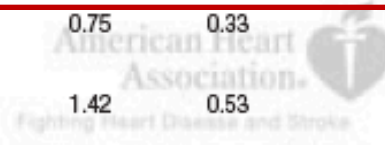
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	Patients With Periprocedural Silent Cerebral Ischemic Lesion	Patients Without Periprocedural Cerebral Ischemic Lesion	OR	95% CI, Lower Limit of OR	95% CI, Upper Limit of OR	P
No. of patients	33	198				
Mean age, y	60±8	58±10	1.02	0.98	1.06	0.285
Male gender	24 (73)	156 (79)	0.74	0.32	1.72	0.495
Hypertension	17 (52)	95 (48)	1.08	0.52	2.24	0.828
Diabetes mellitus	0	10 (5)	0.00	0	Low	0.991
Structural heart disease	6 (18)	24 (12)	1.55	0.58	4.13	0.378
Dyslipidemia	8 (24)	49 (25)	0.93	0.39	2.20	0.879
Previous stroke or transient ischemic attack	2 (6)	13 (7)	1.37	0.37	5.11	0.633
Type of AF						
Paroxysmal	20 (61)	117 (59)	0.89	0.42	1.88	0.77
Persistent	13 (39)	81 (41)				
Antithrombotic drugs						
Warfarin	23 (70)	154 (78)	0.68	0.30	1.54	0.361
Aspirin	10 (30)	44 (21)				
CHADS score						
0	15	92	Base	Base	Base	Base
1	16	83	1.18	0.55	2.53	0.668
2	0	16	0.38	0.04	3.10	0.369
>2	2	7	2.04	0.37	11.08	0.407
Spontaneous echo contrast	3	5	3.86	0.87	16.99	0.074
Mean ACT value during the procedure, s	269±28	282±32	0.98	0.97	0.99	0.014
Type of procedure		95 (48)	0.75	0.33	1.73	0.511
PV isolation	13 (39)	73 (37)				
PV+linear lesion	12 (37)	30 (15)	1.42	0.53	3.79	0.473
PV+linear lesion+atrial fragmented potential	8 (24)					
Transseptal approach	27 (79)	169 (85)	0.58	0.24	1.40	0.226
Patent foramen ovale	6 (21)	29 (15)	1.5	0.60	3.79	0.379
Procedure time, min	196±96	180±80	1.00	0.99	1.00	0.336
Radiofrequency time, min	50±20	47±20	1.00	0.99	1.00	0.336
Electric or pharmacological cardioversion during ablation	15 (45)	46 (23)	2.75	1.29	5.89	0.009



# **Incidence of Silent Cerebral Thromboembolic Lesions After Atrial Fibrillation Ablation May Change According To Technology Used: Comparison of Irrigated Radiofrequency, Multipolar Nonirrigated Catheter and Cryoballoon**

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STEFFEN FROEHNER, M.D.,¶ VOLKER ZIEGLER, M.D.,# DOMENICO SERGI, M.D.,†  
FEDERICO CESARANI, M.D.,\*\* and ALESSANDRO BLANDINO, M.D.,\*,†

Studio NON randomizzato che confronta le 3 tecnologie in merito ai findings radiologici pre e post-procedurali in acuto

-Catetere Irrigato	(36 pt)
-CryoPallone	(36 pt)
-PVAC	(36 pt)

I pazienti sono stati sottoposti a RMI prima e dopo la procedura

Catetere Irrigato

PVAC

CryoPallone

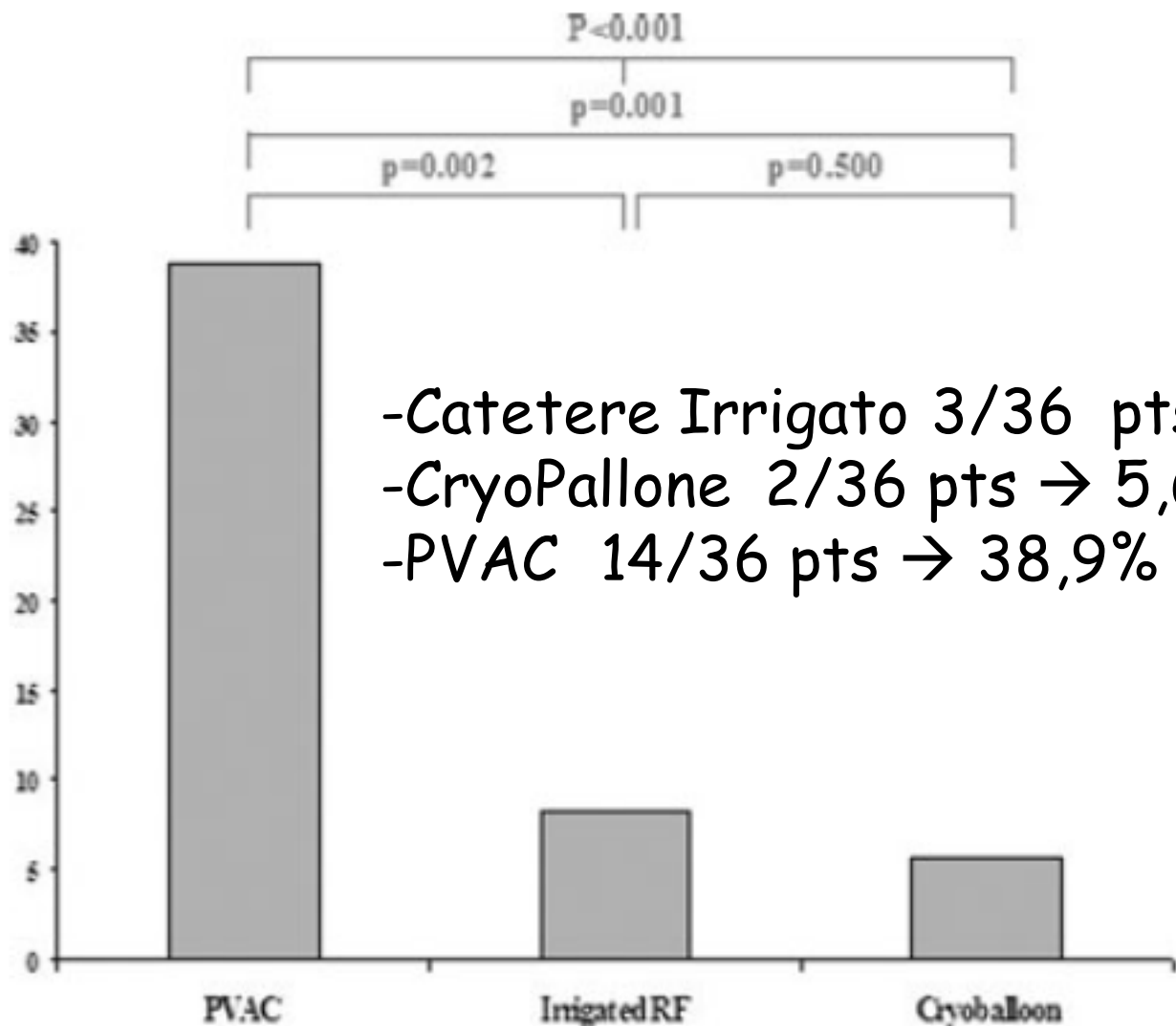
**TABLE 1**

Clinical and Procedural Characteristics of Population Divided into 3 Groups According to the Type of Ablation Technology

Population	Group 1, 36 pts	Group 2, 36 pts	Group 3, 36 pts	P
Gender (male)	24 (67%)	23 (64%)	25 (69%)	0.882
Mean age (years)	57 ± 7	57 ± 9	55 ± 12	0.713
Hypertension	19 (53%)	12 (33%)	20 (57%)	0.120
Dyslipidemia	11 (31%)	5 (14%)	13 (36%)	0.09
Dysthyroidism	8 (22%)	2 (6%)	4 (11%)	0.10
Left ventricular ejection fraction (%)	64 ± 4	62 ± 4	63 ± 7	0.218
Left atrium antero-posterior diameter (mm)	43 ± 6	45 ± 6	41 ± 5	0.189
First documentation (months)	80 ± 55	47 ± 30	61 ± 53	0.165
Procedural duration (minutes)	123 ± 45	127 ± 53	147 ± 32	0.137
Fluoroscopy time (minutes)	16 ± 14	20 ± 10	37 ± 18	0.001
Mean ACT (seconds)	310 ± 49	320 ± 49	304 ± 52	0.074



# Incidenza dei findings neuro-radiologici



- Catetere Irrigato 3/36 pts → 8,3%
- CryoPallone 2/36 pts → 5,6%
- PVAC 14/36 pts → 38,9%

In tutti i pts in cui l'MRI è risultata positiva NON è stato riscontrato alcun sintomo/deficit cognitivo ad un esame clinico completo neurologico post procedurale e anche il Doppler alle carotidi postprocedurale è risultato negativo

# Incidence of Asymptomatic Intracranial Embolic Events After Pulmonary Vein Isolation

## Comparison of Different Atrial Fibrillation Ablation Technologies in a Multicenter Study

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Studio prospettico osservazionale non randomizzato che confronta le 3 tecnologie in merito ai findings radiologici pre e post-procedurali in acuto

Popolazione e strategia Ablativa: 74 Pazienti (46 PAF, 28 CAF) trattati con:

27 Irrigato (Carto/NavX + Lasso/Optima);

23 Criopallone;

24 PVAC.

Test Neurologico alla dimissione e 4-5 giorni dopo.

**Table 1 Patient Characteristics**

	Externally Irrigated RF Group (n = 27)	Cryoballoon Group (n = 23)	PVAC (n = 24)	p Value
Age, yrs	61 ± 10	61 ± 7	59 ± 10	0.62
Male	20 (74)	15 (65)	15 (63)	0.65
Hypertension	16 (59)	14 (61)	11 (43)	0.51
Structural heart disease	6 (22): CHD, 3; myocarditis, 1; tachymyopathy, 2	3 (13): CHD, 1; valvular, 1; DCMP, 1	6 (25): CHD, 5; DCMP, 1	0.57
Persistent AF	14 (52)	8 (35)	6 (25)	0.13
LA, mm	42 ± 5	40 ± 6	41 ± 5	0.47
Chronic lesions on MRI before ablation	6 (22)	2 (9)	1 (4)	0.16
CHA <sub>2</sub> DS <sub>2</sub> VASc score	1.7 ± 1.5	1.7 ± 1.3	1.3 ± 1.0	0.52

**Table 2 Procedure Characteristics**

	Externally Irrigated RF Group (n = 27)	Cryoballoon Group (n = 23)	PVAC (n = 24)	p Value
Procedure time, min	198 ± 50	174 ± 35	124 ± 32	<0.001
Fluoroscopy time, min	34 ± 17	27 ± 13	24 ± 10	0.035
Ablation time, min	41 ± 14	45 ± 7	25 ± 9	<0.001
Total energy delivered, J	68,240 ± 23,084	—	80,540 ± 43,447	0.28
Atrial fibrillation during the procedure	10 (37)	7 (30)	10 (42)	0.43
Need for cardioversion	8 (30)	5 (22)	10 (42)	0.33

**Table 3** Characteristics of New Embolic Events in All 3 Groups

	Externally Irrigated RF Group (n = 27)	Cryoballoon Group (n = 23)	PVAC (n = 24)
Patients with new embolic events,	2 (7.4)	1 (4.3)	9 (37.5)
No. of embolic lesions/patient	1	1	2.7 ± 1.3
Size of embolic lesions, mm	6	4	6.0 (4.5–8.5)
Localization of embolic lesions	Frontal (right): 1, cerebellar (left): 1	Temporo-occipital (right): 1	Cerebellar: 10 parietal: 5 occipital: 4 frontal: 5 *(13 right, 11 left)

L'incidenza di SCE per le tre tecnologie sono: IR (7,4%), Cryo (4,3%) e Phased RF (33,3%).

Tutti i test neurologici sono normali prima e dopo la procedura.

Tutti i findings radiologici **SONO ASINTOMATICI.**

## Gas Bubbles During Ablation (*Electrodes 1 - 10 Interaction*)

- Gas bubble output observed in animal study when electrodes 1 and 10 come in very close proximity

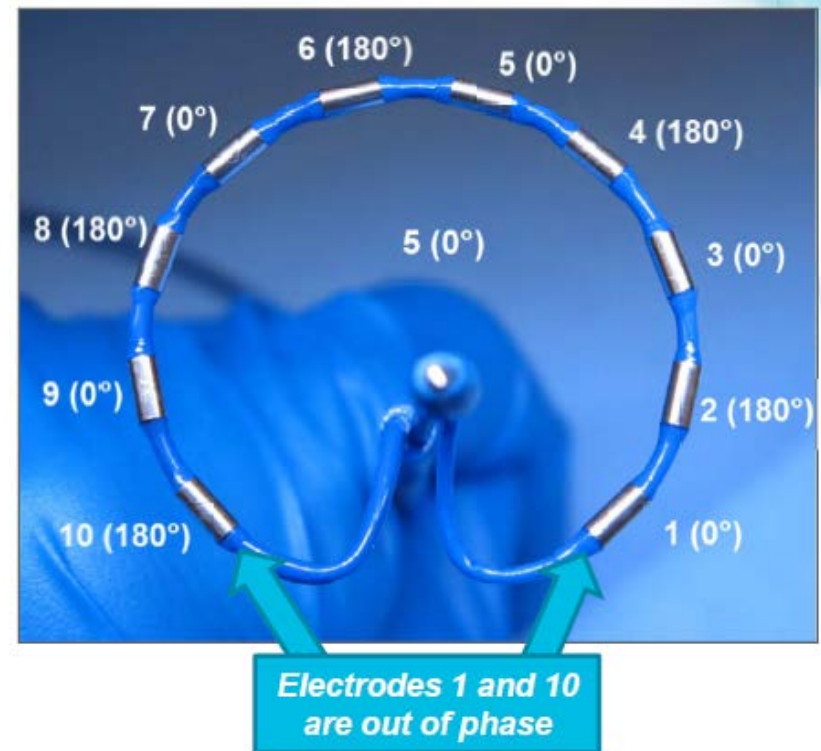
### Technical Explanation

- Bipolar energy delivery occurs because adjacent electrodes are out of phase.
- In any mode other than unipolar electrode 1 and 10 are out of phase with respect to each other
- If they are too close to one another higher than expected current densities may occur resulting in higher than expected temperatures
- If the electrodes come in contact a system notice is triggered and ablation on that channel is stopped

-Observed a large reduction in gas volume produced in the animal model when the following techniques were used to avoid 1/10 interaction

-Prior to ablation, ensure the electrodes are separated by at least as much distance as is present when the array is in the neutral position.

- If there is uncertainty regarding the proximity of electrodes, turn off or do not select one of the pairs



# DWI MRI Following Phased RF Ablation of AF: Low Cerebral Lesion Rate (Nardi et al, Boston AF 2012)

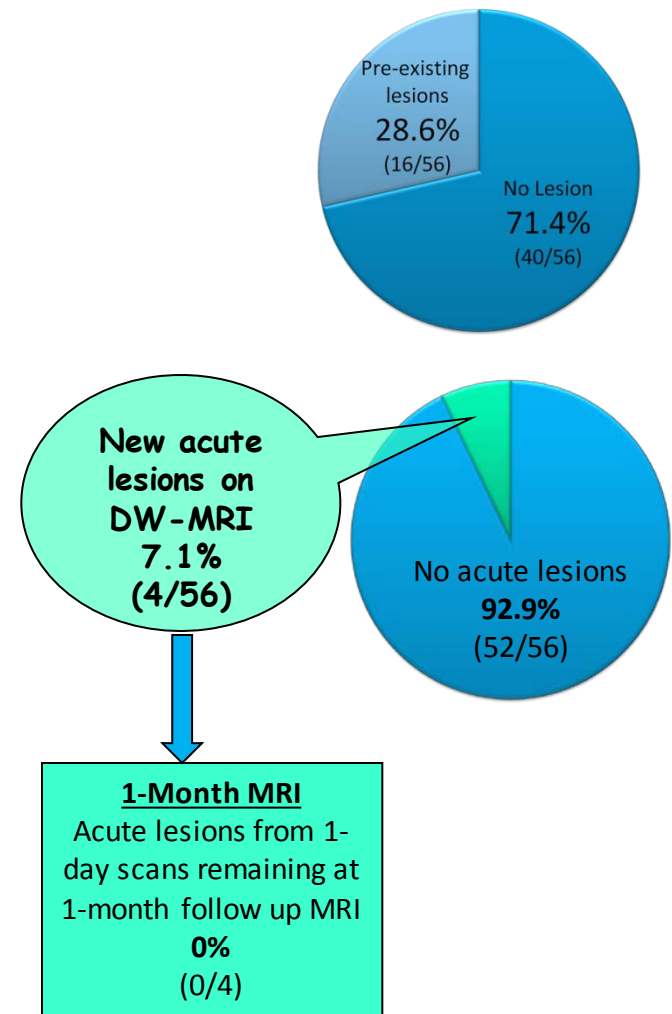
**N = 56 patients, 32% persistent AF**

**DW-MRI & T1/T2 scans done before and 1 day post-ablation**

**DW-MRI & T1/T2 scans 30 days post ablation for patients with acute lesions**

**Key differences from earlier reports:**

- ACT  $\geq$  300s throughout procedure
- Careful flushing and aspiration of sheaths before catheter advancement and sheath resident in right atrium much of the procedure
- Attention to proximity of electrodes 1 and 10
- Deselecting electrode pairs with poor contact or distal PV position





# Asymptomatic Silent Cerebral Embolism

Author	Cryo	Phased RF	Irrigated RF	8 mm Tip	Other
Nardi et al. <sup>14</sup> Boston AF 2012 Poster		4/56 (7.1%)			
Di Biase et al. <sup>15</sup> AHA 2011 Poster			1/51 (1.9%)		
Rillig et al. <sup>16</sup> (IRF Robot Assist) AHA 2011 Session 12062			3/20 (15.0%)		9/50 (18.0%)
Hioki et al. <sup>17</sup> ESC Poster P3597 EHJ 2011			13/51 (25.5%)		
Deneke et al. <sup>18</sup> HRJ 2011		30/72 (41.7%)	3/14 (21.4%)		
McClelland et al. <sup>19</sup> (S. Clamp) HRS Poster HRJ 2011					5/25 (20.0%)
Aso et al. <sup>20</sup> HRS Poster HRJ 2011			17/71 (23.9%)	14/31 (45.2%)	
Mizukami et al. <sup>21</sup> HRS Poster HRJ 2011			18/47 (38.3%)		
Herrera Siklody et al. <sup>22</sup> JACC 2011	1/23 (4.3%)	9/24 (37.5%)	2/27 (7.4%)		
Gaita et al. <sup>23</sup> JCE 2011	2/36 (5.6%)	14/36 (38.9%)	3/36 (8.3%)		
Gaita et al. <sup>24</sup> Circulation 2010			33/231 (14.3%)*		
Neumann et al. <sup>25</sup> Europace 2011	4/45 (8.9%)		3/44 (6.8%)		
Schrickel et al. <sup>26</sup> Europace 2010			6/53 (11.3%)		
Lickfett et al. <sup>27</sup> JCE 2006			1/10 (10.0%)		
Range	[4.3% - 8.9%]	[7.1% - 41.7%]	[1.9% - 38.3%]	[45.2%]	[18.0% - 20.0%]

# Deneke, Hearth Rhythm 2011

## Post-Ablation Asymptomatic Cerebral Lesions – Long-term Follow-Up Using Magnetic Resonance Imaging

L'obiettivo dello studio è quello di investigare nel follow up il decorso clinico e le caratteristiche dei findings radiologici rilevati con la RMN il giorno dopo la procedura di ablazione della FA.

### **Metodi:**

La popolazione è costituita da 86 pazienti (55 PAF e 31 CAF), 72 dei quali trattati con tecnologia Phased RF (solo PVAC nei PAF e PVAC, MASC e MAAC nei CAF) e i rimanenti 14 con catetere irrigato (Carto + Lasso).

Le RMN sono state effettuate:

- Il giorno prima della procedura
- 24-48 ore dopo la procedura
- da 2 settimane ad un anno dopo la procedura

I pazienti con RMN positiva per ASCE, sono stati sottoposti ad un esame neurologico dopo la procedura e al Follow Up.

## Risultati in acuto:

-in 33/86 pazienti sono stati riscontrati 119 ASCE

- Incidenza **PVAC**: **42%** (30/72); **IRF**: **21%** (3/14)

- gli esami neurologici sono normali in tutti i pazienti

### **Risultati nel Follow Up:**

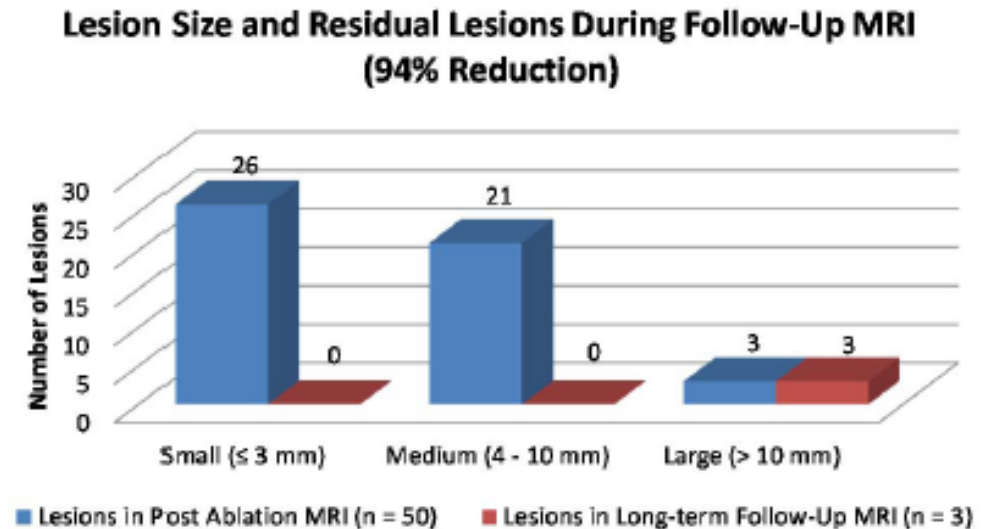
- Dei 33 pazienti con ASCE, 14 (11 PVAC e 3 IRF) hanno partecipato al follow up (comprendente l'esame neurologico e la RMN)
- gli esami neurologici ripetuti nel Follow Up non hanno evidenziato deficit di alcun tipo nè alterazioni.
- In questi 14 pazienti erano stati riscontrati in acuto 50 findings radiologici, così suddivisi:
  - 26 small ( $\leq 3$ mm)
  - 21 medium (da 4mm a 10mm)
  - 3 large ( $> 10$ mm)

La totalità delle lesioni piccolo-medie (94% delle lesioni totali) regredisce nel Follow Up e solo le 3 lesioni grandi (6% del totale) sono ancora presenti.

**Queste lesioni di dimensioni maggiori sono riscontrabili in**

**2/11 pazienti PVAC (18%) e in**

**1/3 (33,3%) pazienti IRF.**



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