



Anti Thrombotic Therapy: Ablation of AF and Left Atrial Flutter

Andrea Natale MD

**Executive Medical Director, Texas Cardiac Arrhythmia Institute,
St. David's Medical Center, Austin, Texas**

Professor of Medicine, Dell Medical school, Austin, Texas

Director of Interventional EP, Scripps Green, San Diego, CA

Clinical Professor, Case Western Reserve University, Cleveland, Ohio

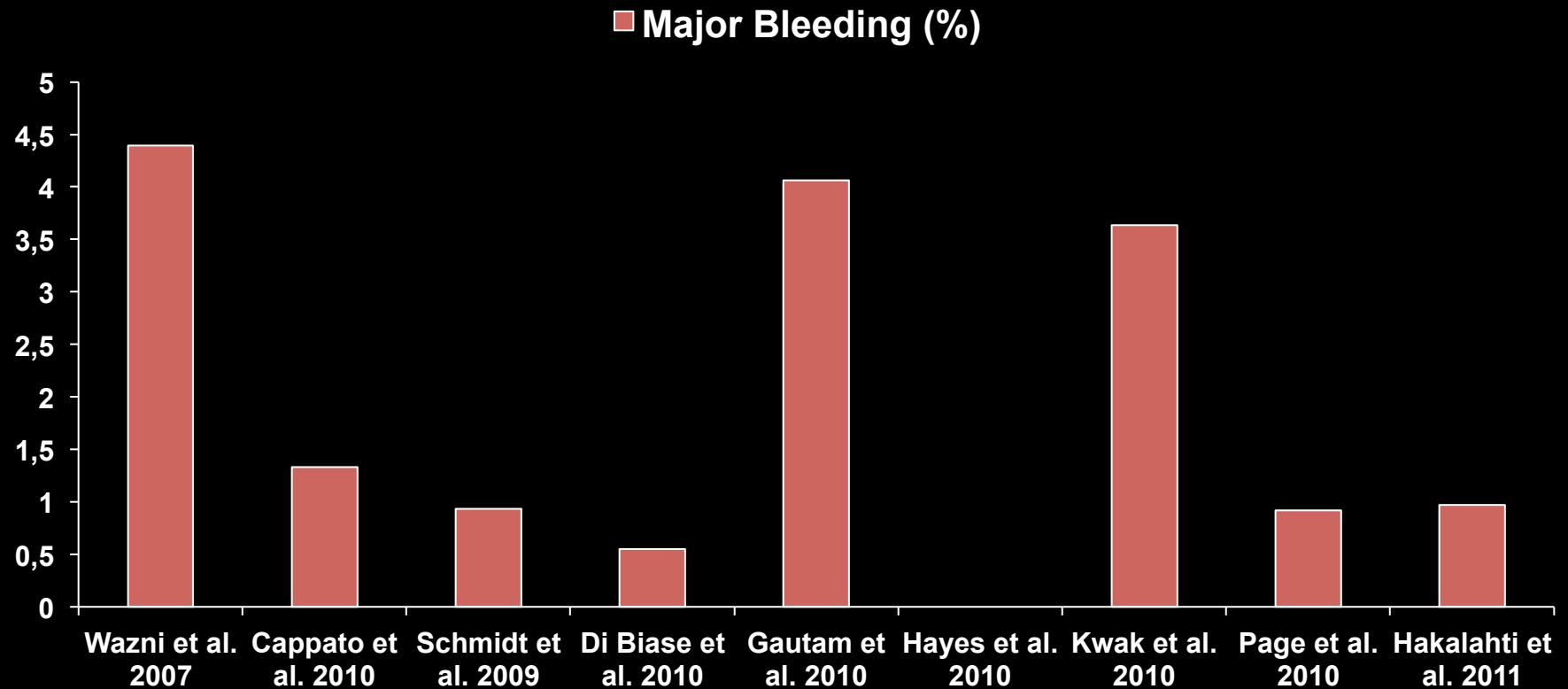
Consulting Professor, Stanford University, Palo Alto, California

Senior Medical Director, AF & Arrhythmia Center, CPMC, San Francisco

Bleeding Complications

- Puncture site hematoma
- Retroperitoneal Bleeding
- Pseudoaneurysm
- Pericardial effusion
- Pericardial tamponade

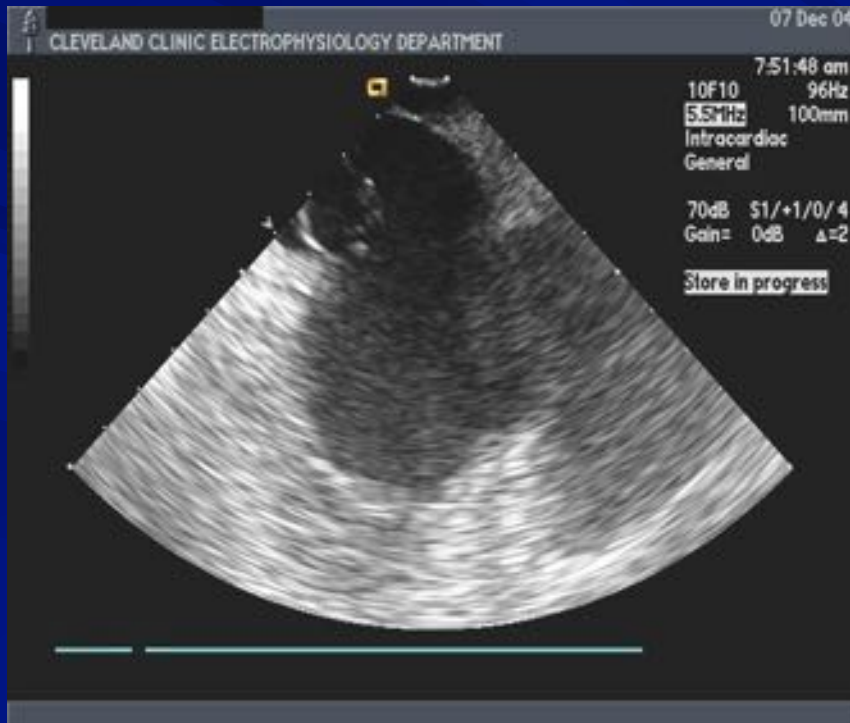
Periprocedural Risk of Major Bleeding during AF Ablation (warfarin discontinuation)



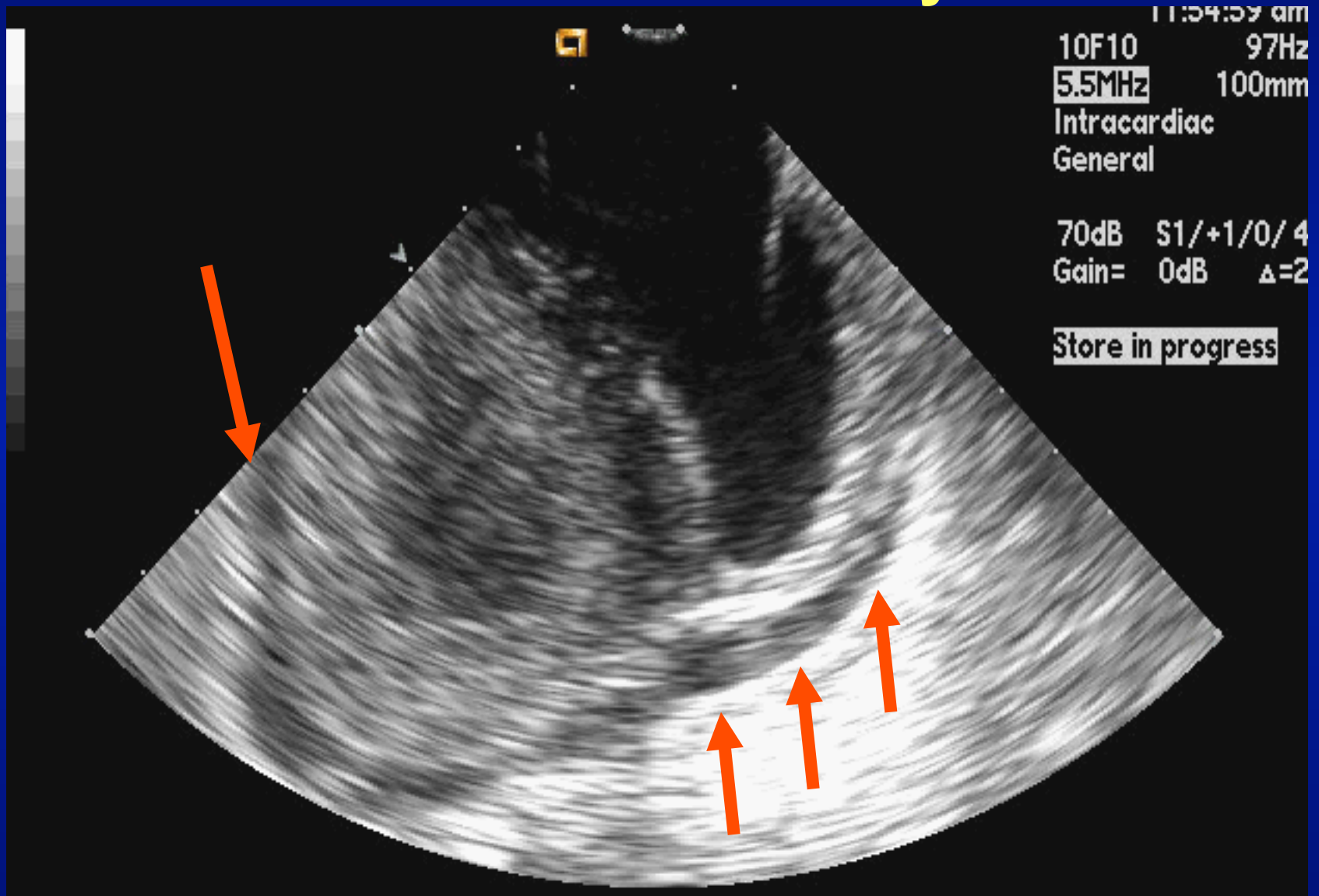
Cardiac Perforation / Tamponnade

- Incidence: 1-3%
- Related to TS puncture, catheter navigation, RF delivery in addition to anticoagulation
- Pericardial effusion: up to 25%
- More common with the OIC.
- Common perforation sites: LAA, LA roof , Mitral isthmus.

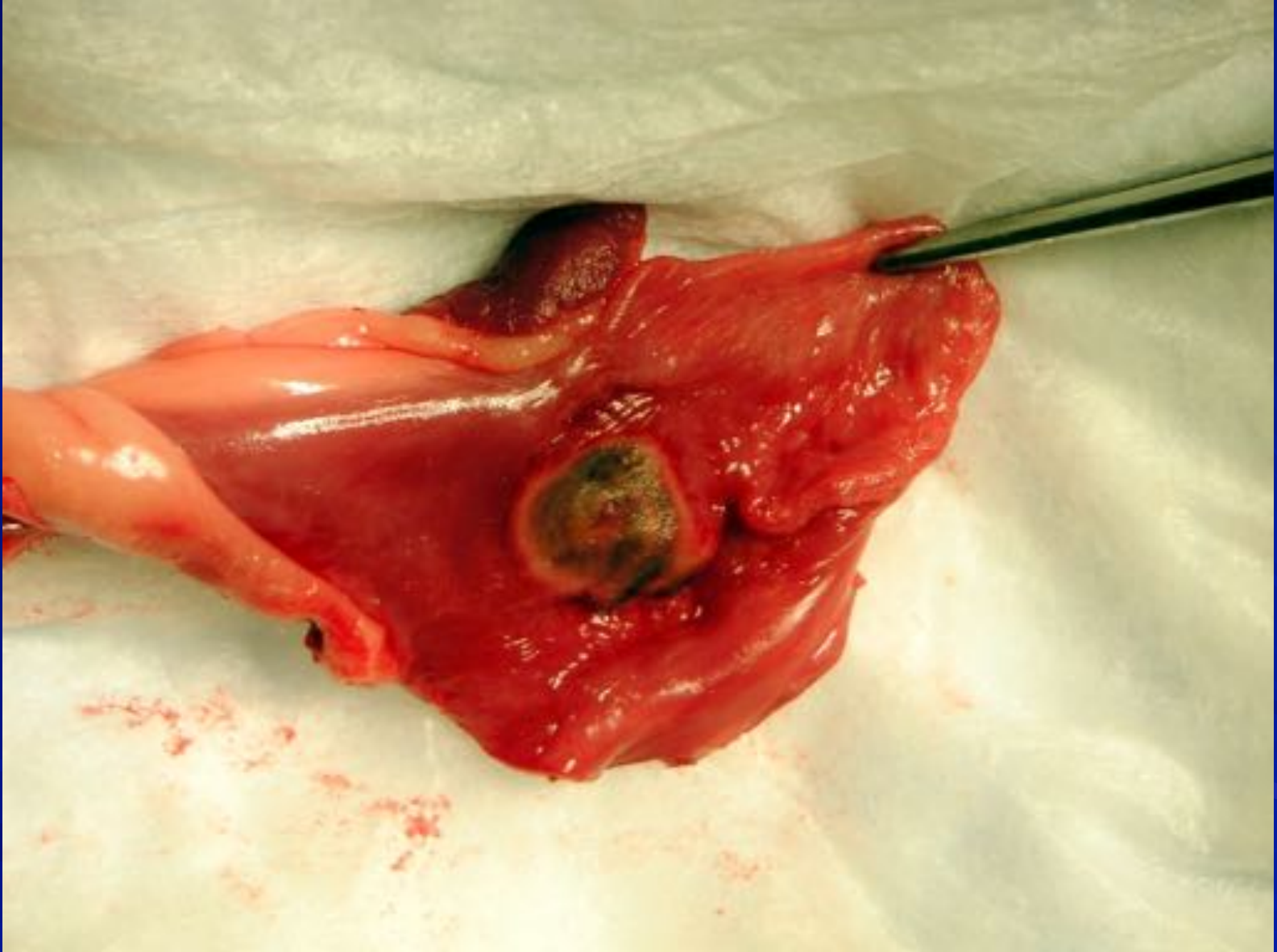
IAS Aneurysm



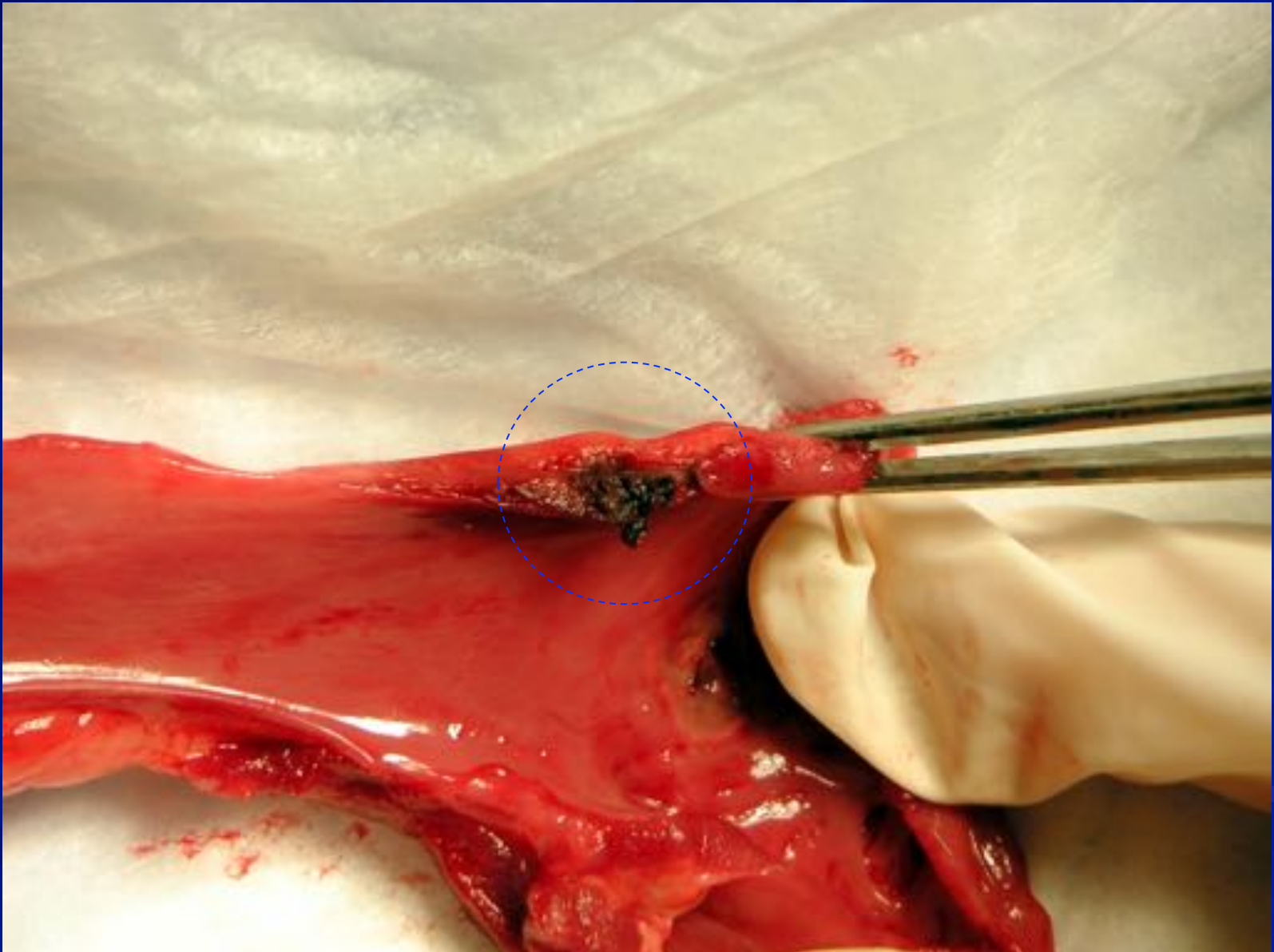
Pericardial Effusion by ICE



LA-LAA junction lesion, epicardial side



LSPV lesion, popping(+)



Prevention

- Pre-prepare the subxyphoid area
- Transseptal puncture: ICE Guidance
- Use RF needle for transeptal
- Monitor with ICE during the procedure
- Monitor and titrating energy delivery to avoid pops. (impedance change, bubble formation).
- Keep contact force below 20 grams

Power Protocol with Open Irrigation

- Start at 40 w
- Reduce the power to 30-35w on the esophagus
- Power application 20 sec
- Keep contact force below 20 grams
- Do not increase the power when perpendicular to the atrial wall
- Monitor the impedance

RF Catheter ablation:

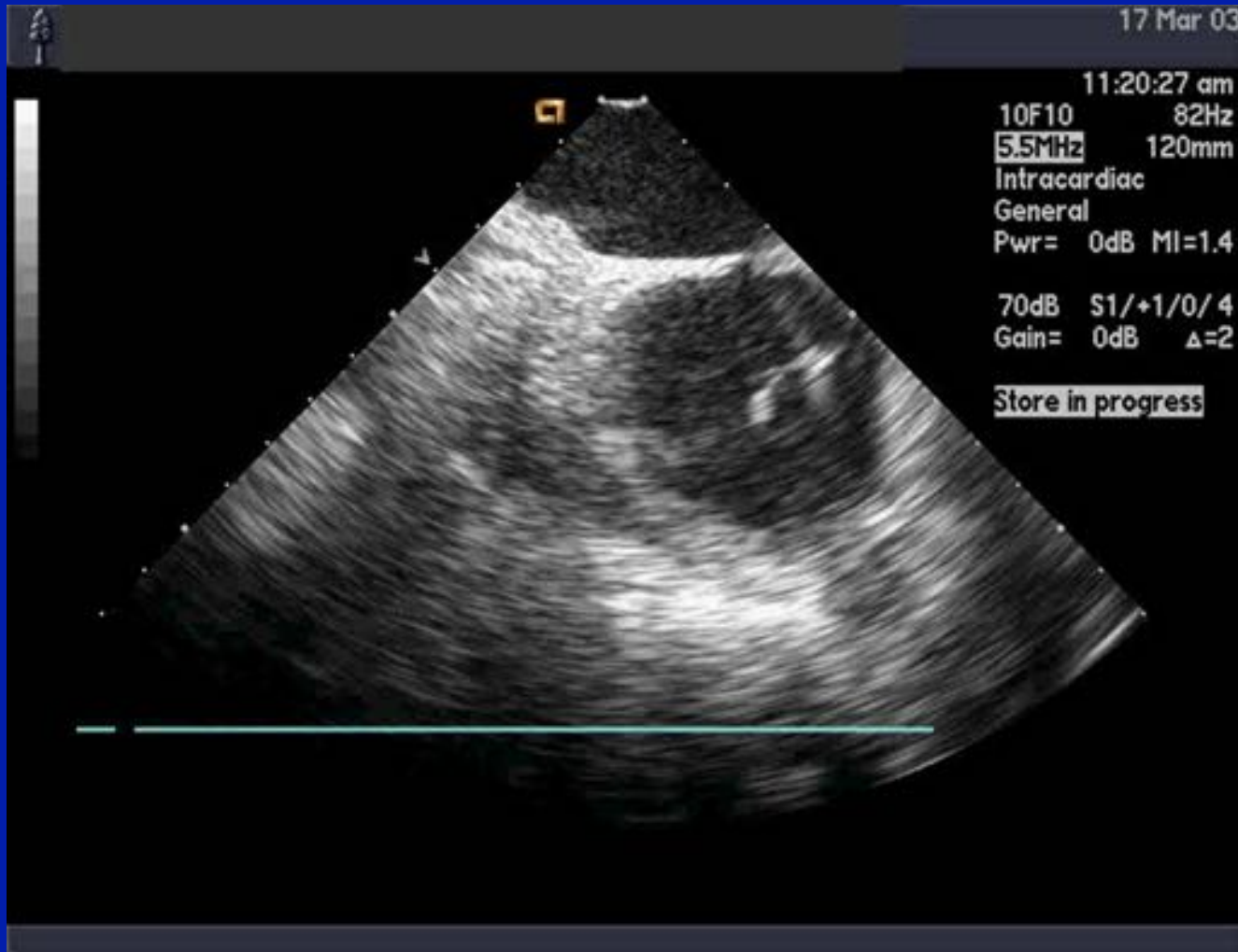
Thromboembolic complications

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graph TD; A[Thromboembolic complications] --> B[Char formation, Air Embolism, RF Time]; A --> C[Soft Thrombus formation];
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Char formation,
Air Embolism,
RF Time

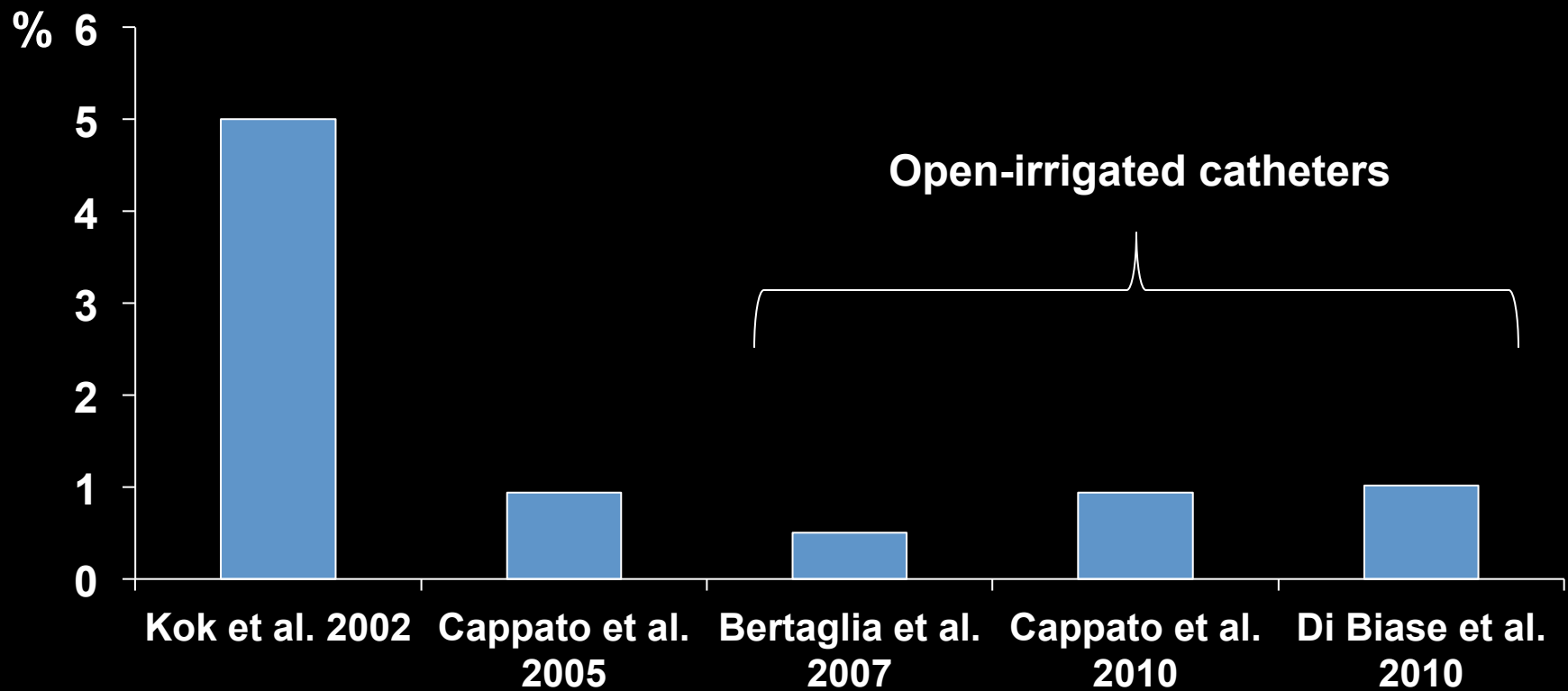
Soft Thrombus
formation

Intra-procedural early detection of complications



ACT < 350 sec; between 1.5 and 12% after Transseptal access

AF ablation and Periprocedural Stroke: an Ominous Association



Cappato et al. Circulation 2005;111:1100

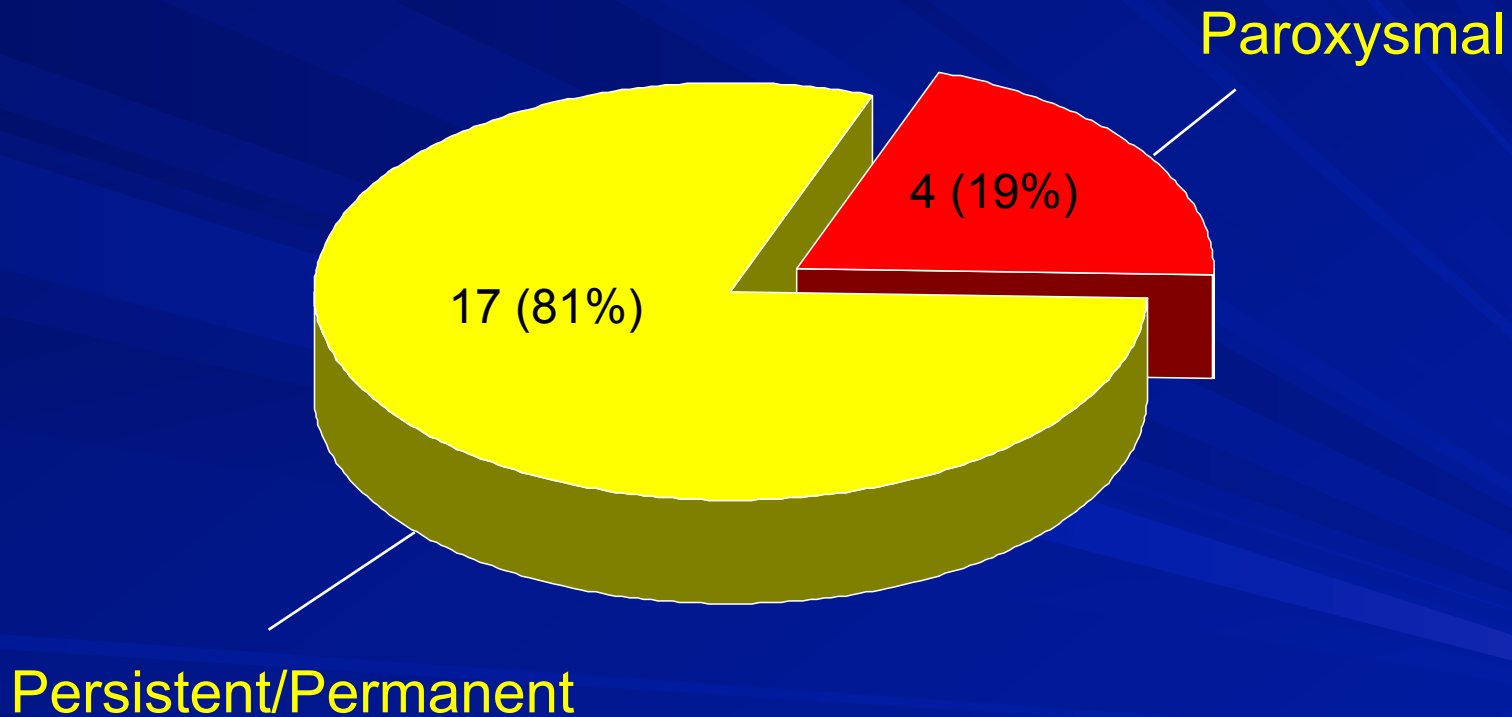
Bertaglia et al. Heart Rhythm 2007;4:1265-71

Cappato et al. Circulation AE 2010;3:32-38

Di Biase et al. Circulation 2010;121:2550-56

Kok et al. JCE 2002;13:764-67

Type of atrial fibrillation in stroke patients



Circulation

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**Atrial Fibrillation Ablation in Patients With Therapeutic International
Normalized Ratio: Comparison of Strategies of Anticoagulation Management in
the Periprocedural Period**

Oussama M. Wazni, Salwa Beheiry, Tamer Fahmy, Conor Barrett, Steven Hao, Dimpri
Patel, Luigi Di Biase, David O. Martin, Mohamed Kanj, Mauricio Arruda, Jennifer
Cummings, Robert Schweikert, Walid Saliba and Andrea Natale

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Patient Characteristics

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 | <i>P</i> |
|-------------------|--------------------------------------|----------------------------------------|------------------------------|----------|
| 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.

Complications

Table 2. Complications

| | Group 1 (n=105) | Group 2 (n=100) | Group 3 (n=150) | Exact <i>P</i> |
|-------------------------|--------------------|--------------------|--------------------|----------------|
| 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 |

Group 1- LMWH 1 mg/kg BID, Group 2- LMWH 0.5 mg/kg BID,
Group 3- on Warfarin

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Periprocedural Stroke and Management of Major Bleeding Complications in Patients Undergoing Catheter Ablation of Atrial Fibrillation: The Impact of Periprocedural Therapeutic International Normalized Ratio

Luigi Di Biase, J. David Burkhardt, Prasant Mohanty, Javier Sanchez, Rodney Horton, G. Joseph Gallinghouse, Dhanunjay Lakkireddy, Atul Verma, Yaariv Khaykin, Richard Hongo, Steven Hao, Salwa Beheiry, Gemma Pelargonio, Antonio Dello Russo, Michela Casella, Pietro Santarelli, Pasquale Santangeli, Paul Wang, Amin Al-Ahmad, Dimpri Patel, Sakis Themistoclakis, Aldo Bonso, Antonio Rossillo, Andrea Corrado, Antonio Raviele, Jennifer E. Cummings, Robert A. Schweikert, William R. Lewis and Andrea Natale

Circulation 2010;121:2550-2556; originally published online Jun 1, 2010;

Periprocedural Stroke and Management of Major Bleeding Complications in Patients Undergoing Catheter Ablation of Atrial Fibrillation

The Impact of Periprocedural Therapeutic International Normalized Ratio

Luigi Di Biase, MD; J. David Burkhardt, MD; Prasant Mohanty, MBBS, MPH; Javier Sanchez, MD; Rodney Horton, MD; G. Joseph Gallinghouse, MD; Dhanunjay Lakkireddy, MD; Atul Verma, MD; Yaariv Khaykin, MD; Richard Hongo, MD; Steven Hao, MD; Salwa Beheiry, RN; Gemma Pelargonio, MD; Antonio Dello Russo, MD; Michela Casella, MD; Pietro Santarelli, MD; Pasquale Santangeli, MD; Paul Wang, MD; Amin Al-Ahmad, MD; Dimpi Patel, DO; Sakis Themistoclakis, MD; Aldo Bonso, MD; Antonio Rossillo, MD; Andrea Corrado, MD; Antonio Raviele, MD; Jennifer E. Cummings, MD; Robert A. Schweikert, MD; William R. Lewis, MD; Andrea Natale, MD, FHRS, FACC

- **Group 1: Ablation with an 8-mm catheter off warfarin**
- **Group 2: Ablation with an *open irrigated catheter off warfarin***
- **Group 3: Ablation with an open irrigated catheter on warfarin**

Periprocedural Stroke and Management of Major Bleeding Complications in Patients Undergoing AF Catheter Ablation

The Impact of Periprocedural Therapeutic INR

| Complication | Group 1 (n=2488), n (%), 95% CI) | Group 2 (n=1348), n (%), 95% CI) | Group 3 (n=2618), n (%), 95% CI) | P, Multiple Comparison Between Group 3 and Groups 1 and 2 |
|----------------------|-------------------------------------|-------------------------------------|-------------------------------------|--------------------------------------------------------------|
| Stroke/TIA | 27 (1.1, 0.72–1.58) | 12 (0.9, 0.46–1.56) | 0 (0) | <0.05 |
| Minor bleeding | 498 (20, 18.3–21.9) | 256 (19, 16.7–21.5) | 105 (4, 3.3–4.9) | <0.05 |
| Major bleeding | 10 (0.4, 0.19–0.74) | 11 (0.8, 0.41%–1.46%) | 10 (0.4, 0.18–0.70) | >0.05 |
| Pericardial effusion | 11 (0.4, 0.22–0.79) | 11 (0.8, 0.41–1.46) | 12 (0.5, 0.24–0.80) | >0.05 |

Di Biase, Natale et al., Circulation, 2010; 121: 2550-6

Pericardial Effusion Management

| | Patients off Warfarin (n=3836) | Patients on Warfarin (n=2618) | <i>P</i> |
|-------------------------------------------------------|-----------------------------------|----------------------------------|----------|
| Patients with pericardial effusion, n (%), 95% CI) | 22 (0.57, 0.36–0.87) | 12 (0.46, 0.24–0.80) | 0.602 |
| Requiring pericardiocentesis, n (%), 95% CI) | 9 (0.23, 0.11–0.45) | 8 (0.31, 0.13–0.60) | 0.626 |
| Requiring fresh frozen plasma, n (%), 95% CI) | 0 | 8 (0.31, 0.13–0.60) | <0.001 |
| Median blood units for transfusion, n (%), 95% CI) | 1 (0.03, 0.00–0.15) | 3 (0.11, 0.02–0.33) | 0.043 |
| Requiring surgery, n (%), 95% CI) | 3 (0.08, 0.02–0.23) | 1 (0.04, 0.00–0.21) | 0.651 |
| Mean pericardial fluid aspiration, cm ³ | 700 ± 300 | 1200 ± 200 | <0.001 |
| Mean protamine for reversal, mg | 45 ± 15 | 70 ± 15 | <0.001 |

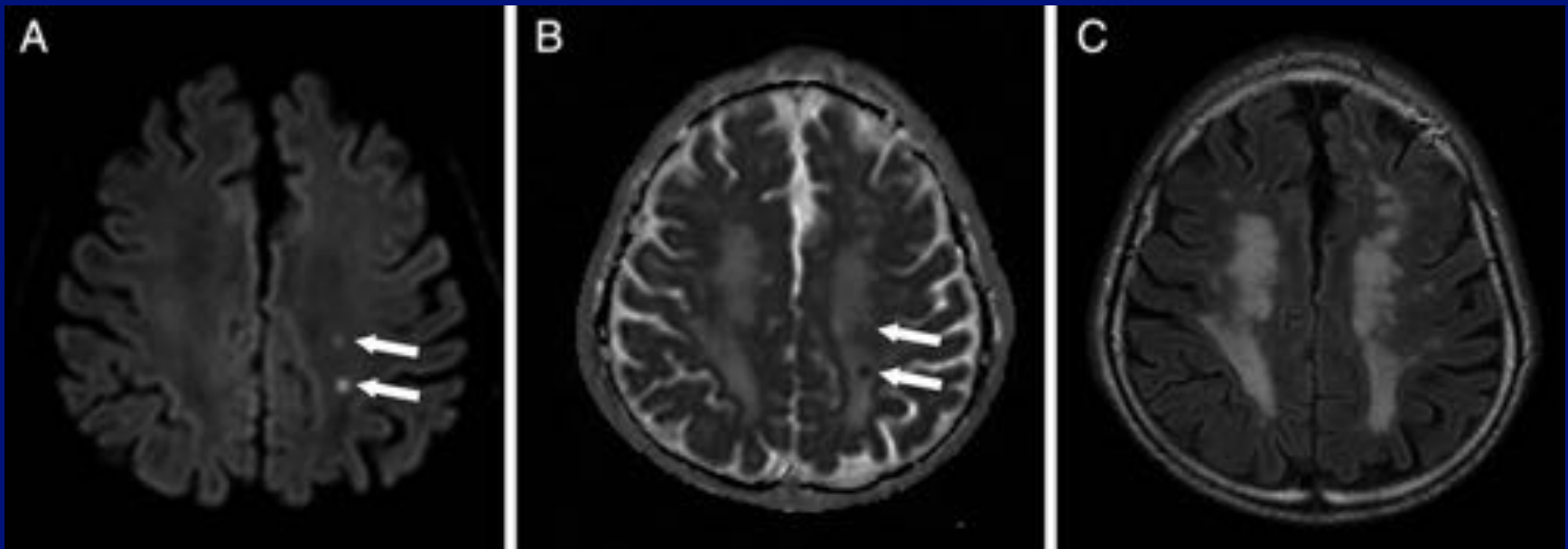
Di Biase, Natale et al., Circulation, 2010; 121: 2550-6

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Silent Ischemia

Periprocedural Clinical Silent Cerebral Ischaemia After PV Ablation.



Schrickel JW et al.: Incidence and predictors of silent cerebral embolism during pulmonary vein catheter ablation for atrial fibrillation. *Europace* 2010; 12: 52-57

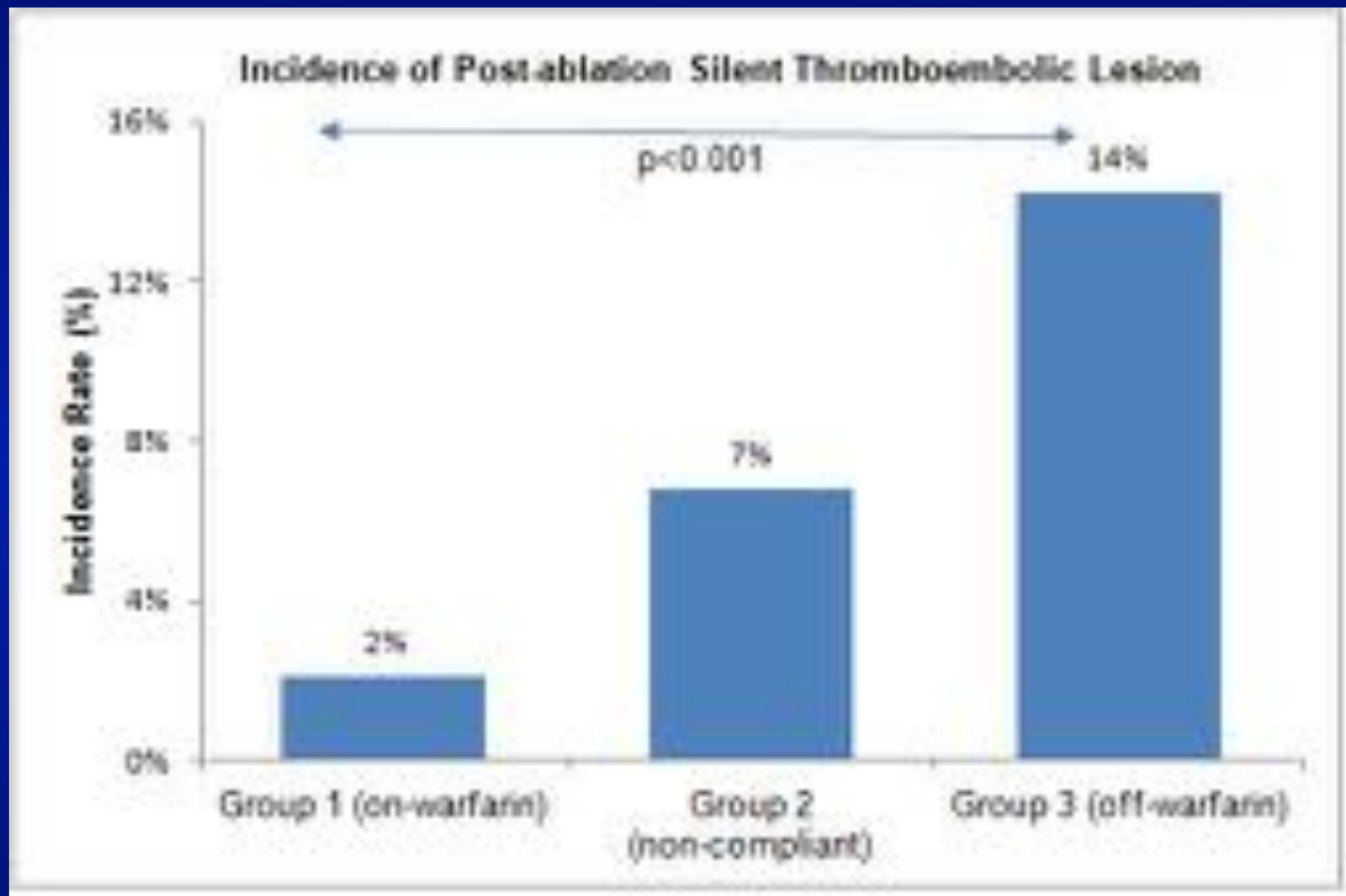
Silent Cerebral Positive Findings

| Publication | ACT | n | Ablation technique | Positive DW MRI |
|----------------------------------------------|---------|---------|----------------------|-----------------|
| Lickfett JCE 2006 | >250 | 10 | Irigated RF ablation | 1 (10%) |
| Schwarz Heart Rythm 2010 | >300 | 13 9 | Irigated RF ablation | 3 (14,3%) |
| Neuman Europace 2010 | >300 | 44 | Irigated RF | 3 (6,8%) |
| | | 45 | Cryoballoon | 4 (8,9%) |
| Gaita Circulation 2010 | 250-300 | 232 | Irigated RF ablation | 33 (14%) |
| Schricket Europace 2010 | >250 | 53 | Irigated RF ablation | 6 (11%) |
| Siklódy Clin Res Cardiol 100, 2011 | >300 | 27 | RF | 2 (7,4%) |
| | | 23 | Cryoballoon | 1 (4,3%) |
| | | 24 | Phased RF | 8 (33%) |
| Gaita JCE 2011 | >300 | 36 | Irigated RF ablation | 3 (8,3%) |
| | | 36 | Phased RF | 14 (38,9%) |
| | | 36 | Cryoballoon | 2 (5,6%) |

Does The Peri-procedural Anticoagulation Management For Af Affect The Prevalence Of Silent Thromboembolic Lesion Detected By Diffusion Cerebral Magnetic Resonance Imaging (dmri) In Patients Undergoing Atrial Fibrillation Ablation With Open Irrigated Radiofrequency Energy? Results From A Prospective Multicenter Study.

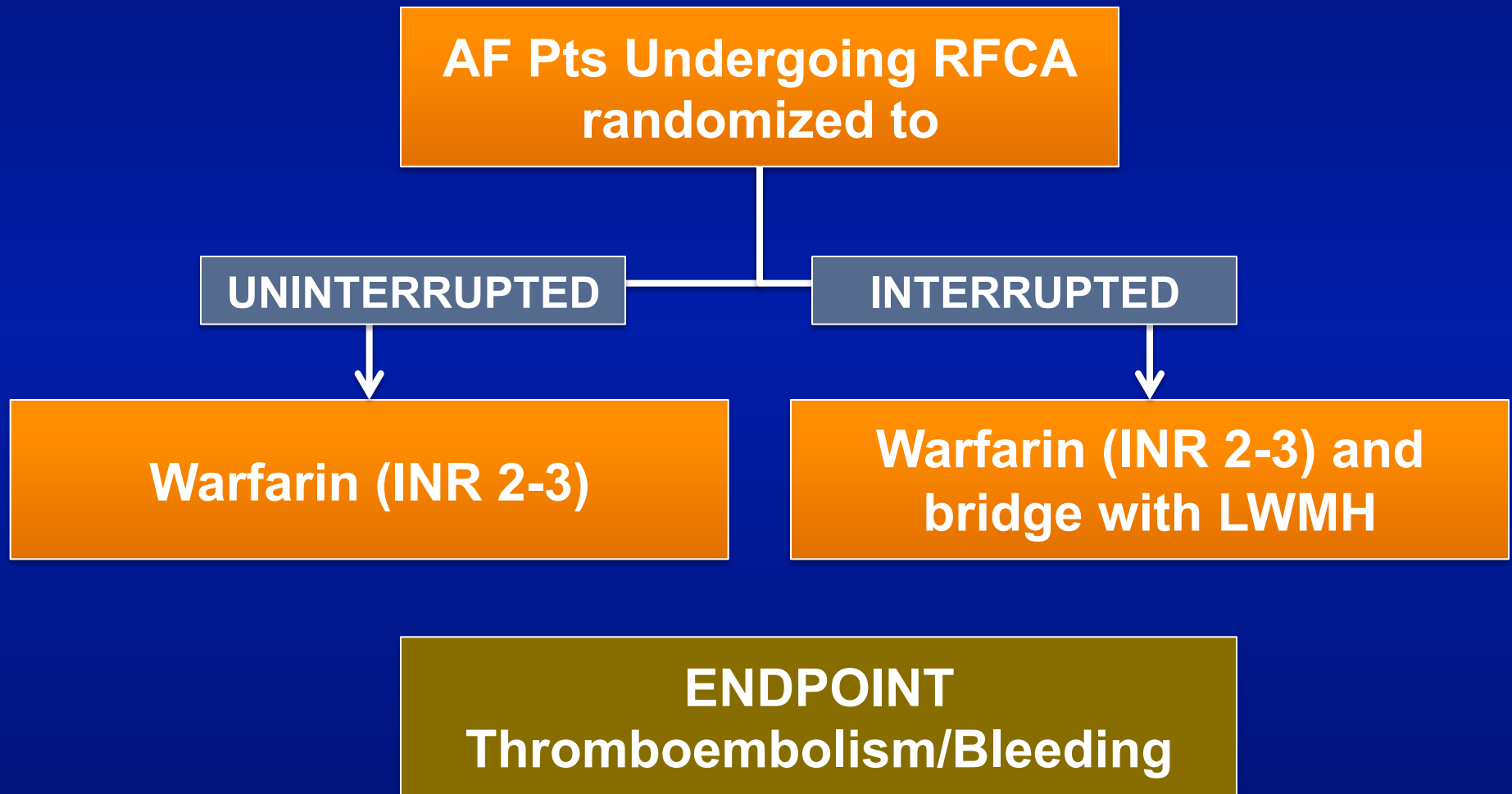
Methods: Consecutive patients undergoing RF ablation for AF with “therapeutic” warfarin and receiving heparin bolus before transseptal (group 1, n=146) were compared with a group of pts that had protocol deviation in terms of maintaining the therapeutic pre-procedure INR (patients with subtherapeutic INR) and/or failure to receive pre-transseptal heparin bolus infusion (non-compliant population, group 2, n=134) and with a group of patients undergoing RF ablation with warfarin discontinuation bridged with low weight molecular heparin (group 3, n=148). All patients underwent preablation and postablation (within 24 hours) dMRI. All patients had to maintain ACT above 300 secs during the entire procedure.

Incidence of Post Ablation Silent Thromboembolic Lesion with Cardioversion



COMPARE STUDY

RCT Continuous vs Discontinuous Warfarin Periprocedural Anticoagulation in pts with High CHAD2S SCORE



Results: Thromboembolic Events

- There were 39 TE [3.7% (29) strokes and 1.3% (10) TIA] events in group 1 respectively:
 - 2 (0.8%) in PAF (paroxysmal),
 - 5 (2.9%) in persistent AF,
 - 32 (8.2%) in LSP AF with a total of **37 TE events in non-PAF.**
- Two (0.25%) strokes in LSP pts were observed in group 2 (p <0.001) with sub therapeutic INR the day of the procedure.
- When stratified by AF type, the event rate for stroke/TIA in PAF was **0.47%** (2/429) compared to **3.2%** (37/1155) in non-PAF; p<0.001.

CONCLUSIONS

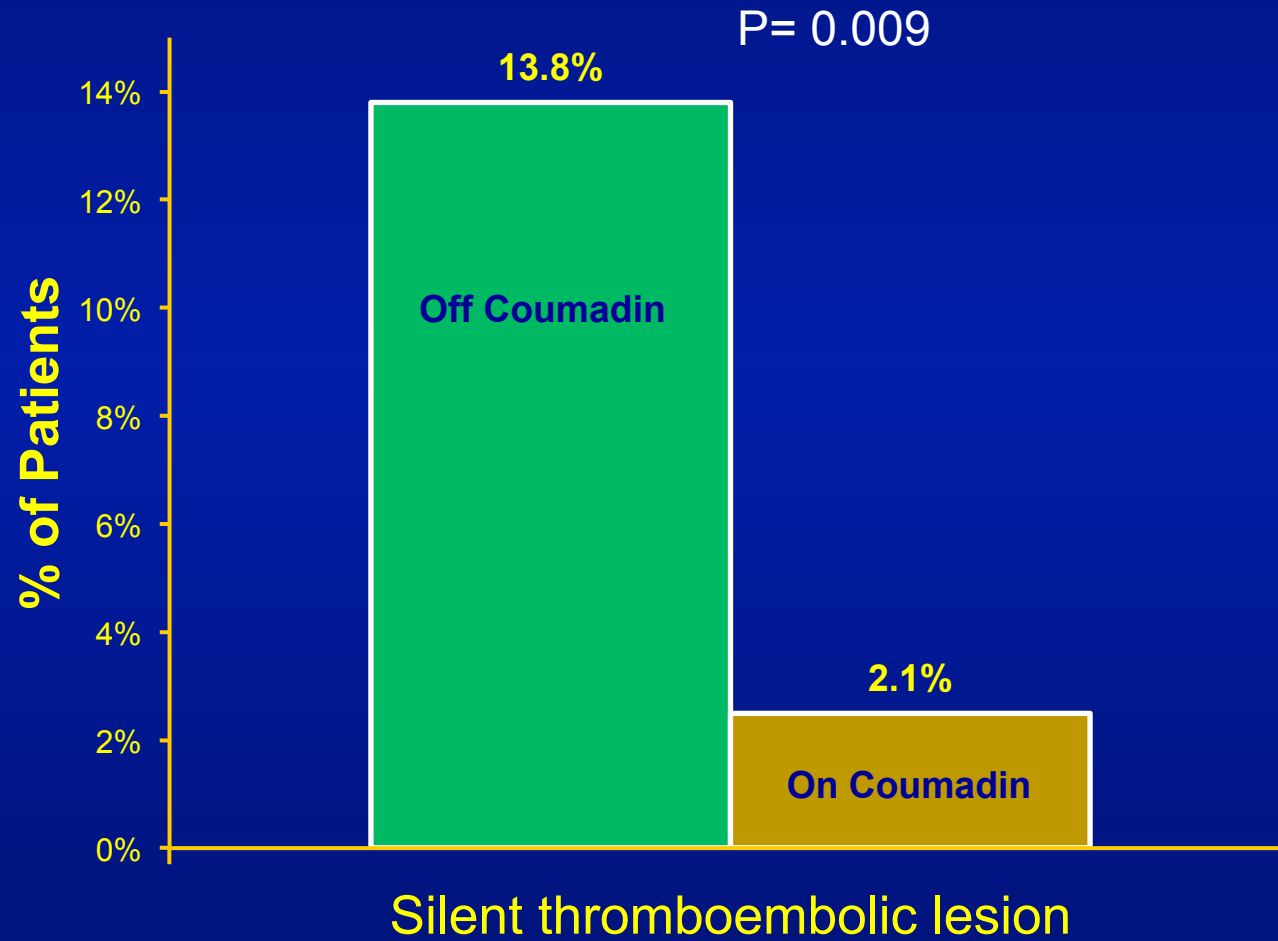
- This multicenter randomized study shows that in higher risk pts therapeutic INR protects against peri-procedural thromboembolic events.
- The risk of these complications during AF ablation is predominantly confined to pts with non paroxysmal AF and especially long standing persistent AF.
- Therefore, future studies assessing the protecting value of newer anticoagulants should be performed in comparison with on warfarin treatment and enrolling pts with LSPAF since in paroxysmal pts these events are relatively rare.

Silent Thromboembolic Lesions Following Catheter Ablation For Atrial Fibrillation Using Radiofrequency Energy: Results From A Sub-study of The "COMPARE" Randomized Trial

Luigi Di Biase, MD, PhD, FACC, FHRS, J.David Burkhardt, MD, Pasquale Santangeli, MD, Prasant Mohanty, MBBS, MPH, Javier E. Sanchez, MD, Rong Bai, MD; Sanghamitra Mohanty, MD; Chintan Trivedi, MD, MPH; Richard Hongo, MD, Steven Hao, MD; Salwa Beheiry, RN; Rodney Horton, MD; Dhanunjaya Lakkireddy, MD, Yaruva Madhu Reddy, MD; Sakis Themistoklakis, MD; Antonio Rossillo, MD; Antonio dello Russo, MD; Jason D. Zagrodzky, MD; Gaetano Fassini, MD; Michela Casella, MD; Giovanni Forleo, MD; Gemma Pelargonio, MD; Claude S Elayi, MD; Maria Lucia Narducci, MD; Claudio Tondo, MD; Robert Schweikert, MD, Andrea Natale, MD, FHRS, FACC

- ❖ Texas Cardiac Arrhythmia Institute at St. David's Medical Center, Austin, Texas, USA;
 - ❖ Department of BME, University of Texas, Austin, Texas, USA;
 - ❖ Department of Cardiology, University of Foggia, Foggia, Italy;
 - ❖ Montefiore Hospital, New York, USA
- ❖ California Pacific Medical Center, San Francisco, California, USA.
 - ❖ University of Miami, Miami, USA;
 - ❖ Kansas University, Kansas City, Kansas, USA;
 - ❖ Akron General Hospital, Akron, Ohio, USA.
 - ❖ Monzino Hospital, Milan, USA

STL



Dabigatran

Feasibility and Safety of Dabigatran Versus Warfarin for Periprocedural Anticoagulation in Patients Undergoing Radiofrequency Ablation for Atrial Fibrillation

Results From a Multicenter Prospective Registry

Dhananjaya Lakkireddy, MD,* Yeruva Madhu Reddy, MD,* Luigi Di Biase, MD, PhD,††§
Subba Reddy Vanga, MD,* Pasquale Santangeli, MD,† Vijay Swarup, MD,|| Rhea Pimentel, MD,*
Moussa C. Mansour, MD,¶ Andre D'Avila, MD, PhD,# Javier E. Sanchez, MD,†
J. David Burkhardt, MD,† Fadi Chalhoub, MD,¶ Prasant Mohanty, MBBS, MPH,†
James Coffey, MD,# Naushad Shaik, MD,** George Monir, MD,†† Vivek Y. Reddy, MD,#
Jeremy Ruskin, MD,¶ Andrea Natale, MD†§‡‡

*Kansas City, Kansas; Austin, Texas; Foggia, Italy; Phoenix, Arizona; Boston, Massachusetts;
New York, New York; Kissimmee and Orlando, Florida; and San Francisco, California*

Methods

Dabigatran Group (cases)

Comprised of 145 consecutive patients on anticoagulation with 150mg of dabigatran etexilate (Pradaxa®) twice daily for at least 30 days before AF ablation

Warfarin group (controls)

An equal number (145) of patients undergoing AF ablation during the same time period, matched on age, gender and type of AF

Patients without therapeutic INR at the time of the procedure were excluded

Methods: On Dabigatran Group

- Patients on dabigatran were instructed to hold the dose on the morning of the procedure.
- Dabigatran was resumed within three hours after hemostasis and when patient was ready to have oral intake after the ablation procedure was completed.

Complications

| | Total (290) | Dabigatran (Cases, n= 145) | Warfarin (Controls, n =145) | p value |
|-------------------------------------------------|-------------|----------------------------------|-----------------------------------|---------------------|
| Major Bleeding Complications | 10 (3%) | 9 (6%) | 1 (1%) | <u>0.019</u> |
| Periprocedural Pericardial Tamponade | 7 (2%) | 6 (4%) | 1 (1%) | 0.120 |
| Late Pericardial Tamponade | 3 (1%) | 3 (2%) | 0 (0%) | 0.250 |
| Minor Bleeding Complications | 20 (7%) | 12 (8%) | 8 (6%) | 0.350 |
| Groin Hematoma | 11 (4%) | 6 (4%) | 5 (3%) | 0.760 |
| Pericardial Effusion without Tamponade | 10 (3%) | 6 (4%) | 4 (3%) | 0.750 |
| Total Bleeding Complications | 29 (10%) | 20 (14%) | 9 (6%) | <u>0.031</u> |
| Embolic Complications (CVA/TIA) | 3 (1%) | 3 (2%) | 0 (0%) | 0.250 |
| Composite of bleeding and embolic complications | 32 (11%) | 23 (16%) | 9 (6%) | <u>0.009</u> |

No intracranial hemorrhage or deaths occurred in the study.

Of note, all 3 thromboembolic complications occurred in non-paroxysmal patients of the dabigatran group while no embolic complications occurred in the warfarin group (p=0.25 for comparison).

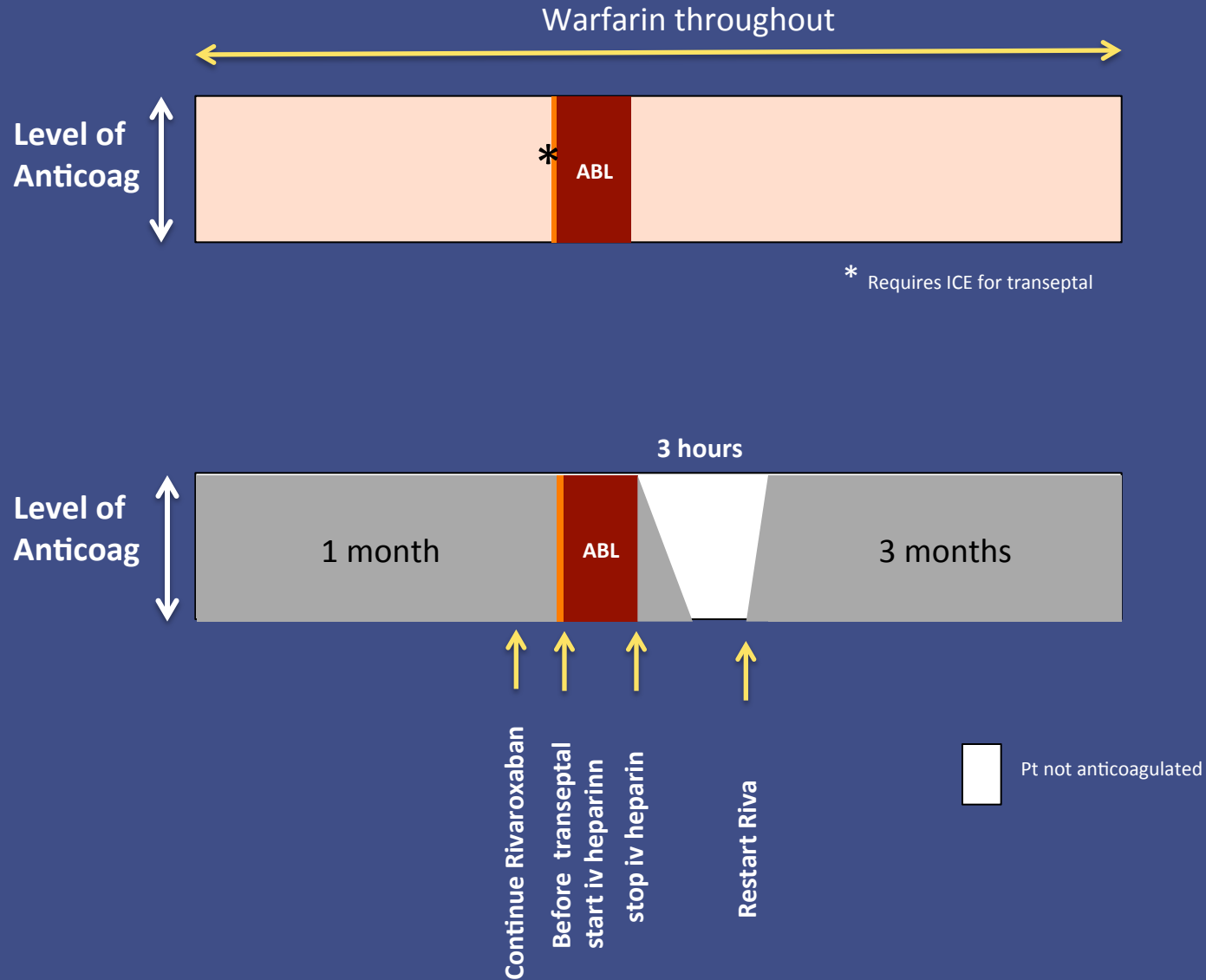
Neurological symptoms improved in all patients with no residual deficits noted at 30 day follow-up.

Rivaroxaban

Feasibility & Safety of Uninterrupted Rivaroxaban vs Warfarin for Periprocedural Anticoagulation in Patients Undergoing Radiofrequency Ablation for Atrial Fibrillation: Results from a Multicenter Prospective Registry

Lakkireddy, Natale, et al JACC 2014

Our Experience with Rivaroxaban



| Baseline characteristics | Group | | p value |
|-----------------------------------------|----------------------------|--------------------|---------|
| | Rivaroxaban n N= 321 | Warfarin N =321 | |
| Age (mean, std dev) | 63 ±10 | 63 ±10 | 0.98 |
| Body Mass Index (mean, std dev) | 30 ± 6 | 30 ±6 | 0.162 |
| Male (%) | 221 (69) | 221 (69) | 1.0 |
| Caucasian (%) | 277 (86) | 292 (91) | 0.06 |
| Paroxysmal Atrial Fibrillation (AF) (%) | 164 (51) | 164 (51) | 1.00 |
| Duration of AF in months; Med (IQR) | 42 (20-81) | 48 (22-84) | 0.243 |
| Re-Do Procedure | 88 (27) | 74 (23) | 0.203 |
| Heart Failure (%) | 30 (7) | 23 (6) | 0.315 |
| Hypertension (%) | 177 (55) | 199 (62) | 0.078 |
| Age > 75 yrs (%) | 41 (13) | 41 (13) | 1.00 |
| Diabetes (%) | 59 (18) | 64 (20) | 0.616 |
| Transient Ischemic Attack or Stroke (%) | 34 (11) | 26 (8) | 0.278 |
| Coronary artery disease (%) | 60 (19) | 67 (21) | 0.488 |
| Peripheral Artery Disease | 17 (5) | 25 (8) | 0.20 |

| Baseline characteristics | Group | | p value |
|-------------------------------------------|-----------------------|--------------------|---------|
| | Rivaroxaban N= 321 | Warfarin N =321 | |
| Mean CHADS2 Score | 1.16 ±1.0 | 1.18 ±1.0 | 0.876 |
| Median CHADS2 | 1 (0-2) | 1 (0-2) | 0.737 |
| Mean CHADSVasc Score | 2.17±1.6 | 2.21 ±1.5 | 0.781 |
| Median CHADSVasc Score | 2 (1-3) | 2 (1-3) | 0.808 |
| Mean HAS BLED Score | 1.47 ±0.9 | 1.70 ±1.0 | 0.032 |
| Mean Left Atrial Size in cm | 4.4 ±0.8 | 4.3 ±0.8 | 0.114 |
| Mean Left Ventricular Ejection Fraction % | 58 ±8 | 57 ±8 | 0.184 |
| Aspirin (%) | 98 (31) | 84 (26) | 0.220 |
| Clopidogrel (%) | 22 (7) | 15 (5) | 0.236 |
| Beta Blocker (%) | 186 (58) | 192 (60) | 0.63 |

Lakkireddy et al. JACC in press

Procedural Variables

| Procedural Variables | Group | | p value |
|--------------------------------------------------|------------------------|--------------------|---------|
| | Rivaroxaban N = 321 | Warfarin N= 321 | |
| Sinus Rhythm on Arrival to the Lab (%) | 209 (65) | 228 (71) | 0.110 |
| Ablation of CFAE/ Posterior Wall | 116 (36) | 125 (39) | 0.463 |
| Additional Linear Lesions including Right Atrial | 101 (31) | 118 (37) | 0.157 |
| Cardioversion during procedure | 102 (32) | 90 (28) | 0.300 |
| Acute PV Isolation (%) | 317 (99) | 314 (99) | 1.0 |
| Procedural Time (min) mean ± SD | 195 ±62 | 198 ±66 | 0.550 |
| Fluoroscopy Time (min) mean ± SD | 49 ±20 | 51 ±30 | 0.320 |
| RF Time (min); mean ± SD | 56 ±25 | 58 ±29 | 0.349 |

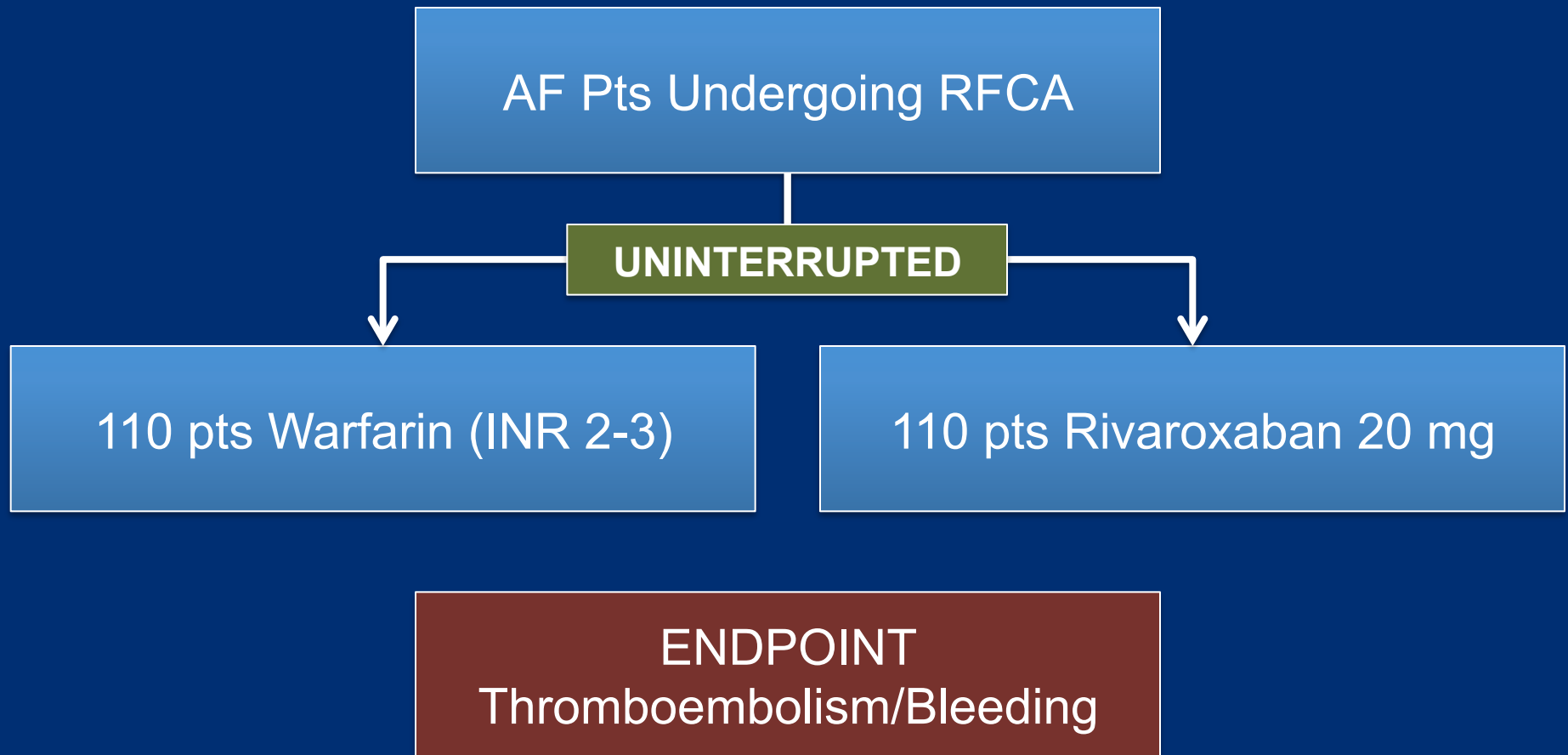
Differences in outcomes

| Outcomes | Rivaroxaban (N =321) | Warfarin (N = 321) | Total (N = 642) | p value |
|--------------------------------------------|-------------------------|-----------------------|--------------------|------------|
| Major Bleeding Complications | 5 (1.6) | 7 (2.2) | 12 (1.9) | 0.772 |
| Early Cardiac Tamponade | 2 (0.6) | 4 (1.2) | 6 (0.9) | |
| Delayed Cardiac Tamponade | 1 (0.3) | 0 (0) | 1 (0.2) | |
| ≥Moderate Access Site Hematomas | 2 (0.6) | 3 (0.9) | 5 (0.8) | |
| Minor Bleeding Complications | 16 (5.0) | 19 (5.9) | 35 (5.5) | 0.602 |
| < Moderate Access Site Hematoma | 13 (4.0) | 18 (5.6) | 31 (4.8) | |
| Insignificant Pericardial Effusions | 3 (0.9) | 1 (0.3) | 4 (0.6) | |
| All Bleeding Complications | 21 (6.5) | 26 (8.1) | 47 (7.3) | 0.449 |
| Thrombo-embolic Complications (Stroke/TIA) | 1 (0.3) | 1 (0.3) | 2 (0.3) | 1.0 |
| Transient Ischemic Attack | 1 (0.3) | 1 (0.3) | 2 (0.3) | |
| Stroke | 0 | 0 | 0 | |
| Bleeding and Thrombo-embolic Complications | 22 (6.8) | 27 (8.4) | 49 (7.6) | 0.457 |
| Other Complications | 3 (0.9) | 2 (0.6) | 5 (0.8) | 1.0 |



- In our multicenter experience, uninterrupted Rivaroxaban appears to be feasible and a safe alternative to uninterrupted warfarin in patients undergoing AF ablation.
- Future larger and randomized trials are needed to confirm our findings

RCT – Warfarin vs. Rivaroxaban for Periprocedural Anticoagulation: Venture AF



Potential Plus and Minus of The Venture AF

- **First Randomized Multicenter Study**
- Include mostly paroxysmal patients
- Small Sample Size
- No MRI Study For Asymptomatic Thromboembolic Events
- Did not mandate pre-transeptal Heparin bolus

Uninterrupted Rivaroxaban reduces the prevalence of Silent Cerebral Ischemia during radiofrequency ablation of AF

Forty nine (49) consecutive patients undergoing ablation of AF while on rivaroxaban 20 mg for at least 3 weeks before the procedure were enrolled in this prospective study.

Twenty four (24) patients discontinued rivaroxaban at least 24 hours before the procedure and were bridged with low molecular weight heparin (GROUP I)

Twenty five (25) patients underwent ablation without rivaroxaban discontinuation (GROUP II) .

Group I patients underwent heparin bolus after transseptal access was obtained, while group II underwent heparin bolus before transseptal. All patients underwent pre and post ablation dMRI.

Uninterrupted Rivaroxaban reduces the prevalence of Silent Cerebral Ischemia during radiofrequency ablation of AF

All 49 patients had persistent and long standing persistent AF.

At post-procedure dMRI, silent thromboembolic lesions were (29.2%) patients in Group I and none in patient in Group II ($p= 0.004$).

Rivaroxaban discontinuation was the strongest predictor of post-procedure SCI.

Uninterrupted rivaroxaban before radiofrequency ablation of AF reduces the prevalence of SCI as detected by dMRI.

A controlled randomized study with a larger sample size is warranted to confirm our findings.

Feasibility and Safety of Uninterrupted Rivaroxaban in Patients Undergoing Radiofrequency Ablation for Long Standing Persistent Atrial Fibrillation

Luigi Di Biase^{1,2,3,4,5,6,7,8,9,10}, MD, PhD; Chintan Trivedi¹, MD, MPH; Prasant Mohanty¹, MBBBS, MPH; Sanghamitra Mohanty¹, MD; Rong Bai¹, MD; Pasquale Santangeli^{1,4}, MD; Javier E. Sanchez¹, MD; Rodney Horton¹, MD; G. Joseph Gallagher¹, MD; Jason Zagrodzky¹, MD; Steven Hao⁵, MD; Richard Hongo⁵, MD; Sabrina Behairy⁵, RN; Dhanunjaya Lakkireddy⁶, MD; Yaruva Madhu Reddy⁶, MD; Juan Viles Gonzalez⁷, MD; J. David Burkhardt¹, MD; Andrea Natale^{1,2,3,4,5,6,7,8,9,10}, MD.

1) Texas Cardiac Arrhythmia Institute at St David Medical Center, Austin, Texas, USA; 2) Albert Einstein College of Medicine, at Montefiore Hospital, New York, USA; 3) University of Texas, Department of Biomedical Engineering, Austin, Texas, USA; 4) Department of Cardiology, University of Pavia, Pavia, Italy; 5) California Pacific Medical Center, San Francisco, California, USA; 6) University of Kansas, Kansas City, 7) State of Illinois Medical Jca of USA, IL; 8) Inland Empire, CA, USA; 9) Case Western Reserve, Ohio, USA; 10) Scripps Clinic, CA, USA

Abstract

Introduction: Peri-procedural anticoagulation management is key to minimize bleeding and thromboembolic complications during and after radiofrequency catheter ablation. Uninterrupted warfarin with warfarin in high risk patients have shown superior over interrupted strategies.

We sought to assess the safety and feasibility uninterrupted rivaroxaban during atrial fibrillation (AF) ablation in patients with long standing persistent atrial fibrillation.

Methods: One hundred and ninety six (196) consecutive patients undergoing AF ablation with uninterrupted rivaroxaban (one dose taken with food the night before the procedure and the following dose taken the night of the procedure) were matched by age and sex with an equal number of patients undergoing AF ablation with uninterrupted warfarin on a "therapeutic range". All patients underwent pulmonary vein isolation and ablation of non-pulmonary vein triggers as dictated by isoproterenol challenge test.

Results: Baseline characteristics and procedural variables were similar between groups. Mean DSR in warfarin group was 1.2 ± 0.1 (CRASH2 score was 1.1 in 141 (72%) in the rivaroxaban group and 130 (66%) in the warfarin patients (p=0.20). One pericardial tamponade and one groin hematoma occurred in rivaroxaban group while 2 patients in warfarin group developed groin hematomas. One TIA with positive MRI was present in the rivaroxaban group.

Conclusions: Uninterrupted rivaroxaban therapy appears to be as safe and efficacious as uninterrupted warfarin strategy in preventing bleeding and thromboembolic events in patients undergoing long standing persistent AF ablation.

Introduction

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We sought to assess the safety and feasibility uninterrupted rivaroxaban during atrial fibrillation (AF) ablation in patients with long standing persistent atrial fibrillation.

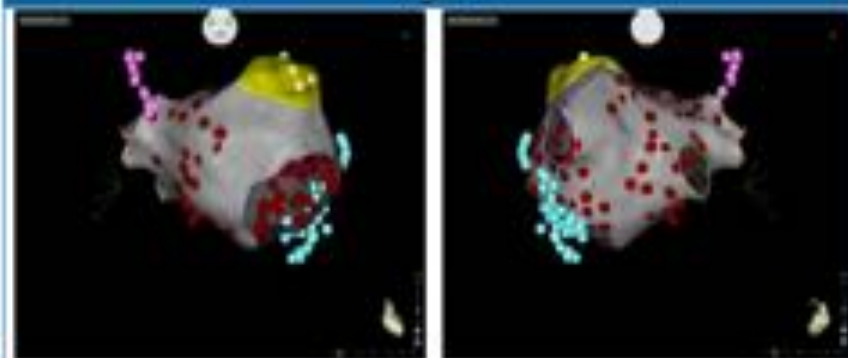
Methods

- One hundred and ninety six (196) consecutive patients undergoing AF ablation with uninterrupted rivaroxaban (one dose taken with food the night before the procedure and the following dose taken the night of the procedure) were matched by age and sex with an equal number of patients undergoing AF ablation with uninterrupted warfarin on a "therapeutic range".
- All patients underwent pulmonary vein isolation and ablation of non-pulmonary vein triggers as dictated by isoproterenol challenge test.

Results

- Baseline characteristics and procedural variables were similar between groups.
- Mean DSR in warfarin group was 1.2 ± 0.1.
- The CRASH2 score was ≥ 2 in 141 (72%) in the rivaroxaban group and 130 (66%) in the warfarin patients (p=0.20).
- One pericardial tamponade and one groin hematoma occurred in rivaroxaban group while 2 patients in warfarin group developed groin hematomas.
- One TIA with positive MRI was present in the rivaroxaban group.

Figure



- Anterior posterior (AP, left panel) and posterior superior (PS, right panel) of a 3D map reconstruction of the left atrium in a patient with long standing persistent atrial fibrillation undergoing extensive ablation, with pulmonary vein isolation and posterior wall isolation (red arrows) plus ablation of non-PV triggers (yellow dots) in the left atrial appendage (yellow dot) (the coronary sinus (light blue dot) and the superior vena cava (green dot)).

Conclusions

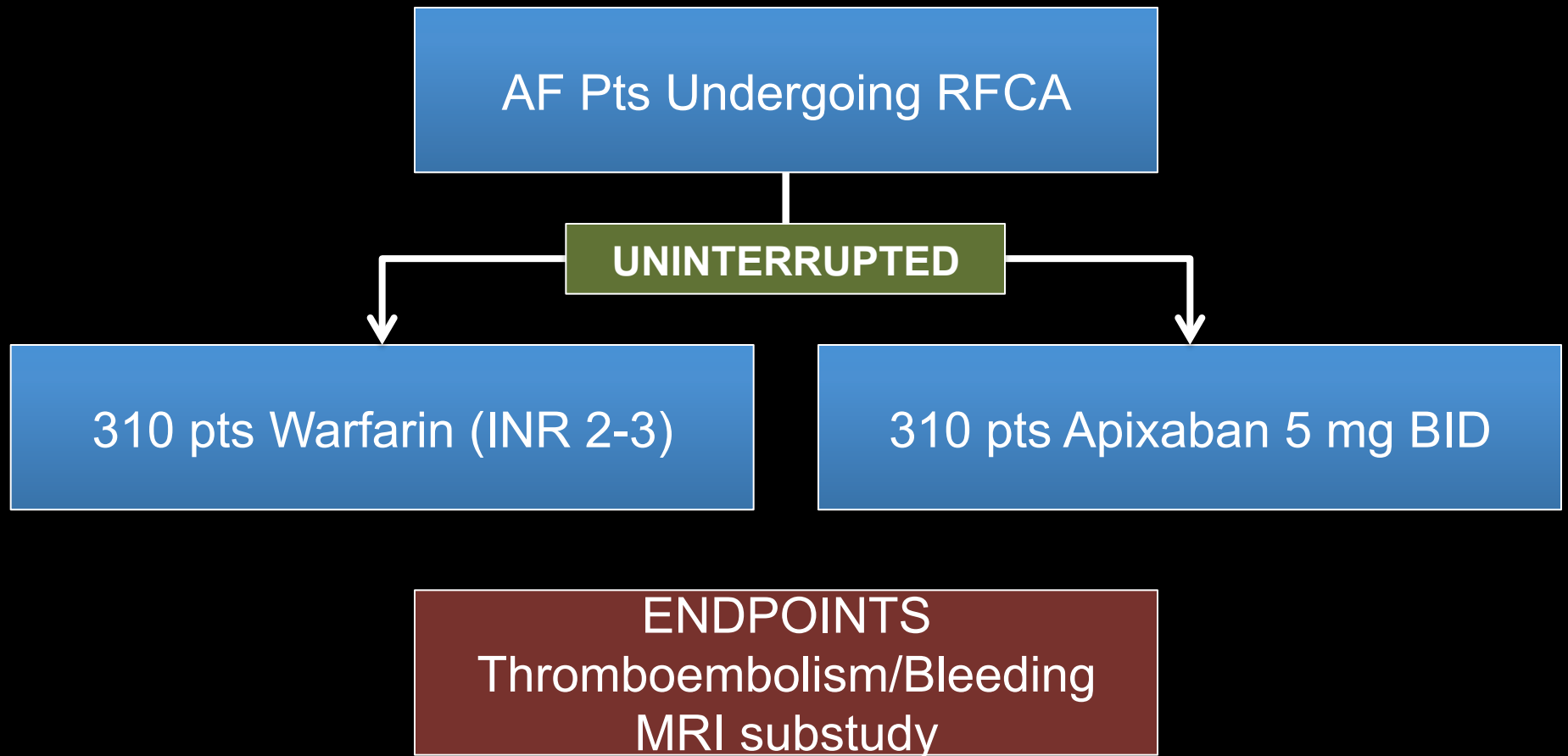
Uninterrupted rivaroxaban therapy appears to be as safe and efficacious as uninterrupted warfarin strategy in preventing bleeding and thromboembolic events in patients undergoing long standing persistent AF ablation.

Disclosures

Dr. Di Biase is a consultant to Texas Medical Devices, Medtronic, St. Jude Medical and several speaker for educational reimbursement from Abbott, Alkermes, EP and Medtronic. Dr. Natale received speaker honorarium from Boston Scientific, Biosense Webster, Medtronic, Johnson and St. Jude. Dr. Natale is a consultant to Biosense Webster, Alkermes and St. Jude Medical. If the speaking activity here is disclosure.

Apixaban

RCT – Warfarin vs. Apixaban for Periprocedural Anticoagulation: AXAFA study



Potential Plus and Minus of The AXAFA Study

- **Randomized Multicenter Study**
- Include Non-paroxysmal patients
- Larger Sample Size
- MRI Study For Asymptomatic Thromboembolic Events
- Does not mandate pre-transeptal Heparin bolus

Feasibility And Safety of uninterrupted peri-procedural Apixaban administration in patients undergoing radiofrequency catheter ablation for atrial fibrillation: Results From a Multicenter Study

Luigi Di Biase^{*†‡§}, MD, PhD; Dhanujaya Lakkireddy^{||}, MD, Chintan Trivedi^{*}, MD, MPH, Thomas Deneke[¶], MD, Martin Martinek[#], MD, Sanghamitra Mohanty^{*}, MD, Prasant Mohanty^{*}, MBBS, MPH, Sameer Prakash^{††}, BS, Rong Bai^{*}, MD, Madhu Reddy, MD^{|||}, Carola Gianni^{*}, MD; Rodney Horton^{*}, MD, Shane Bailey^{*}, MD, Elisabeth Sigmund[#], MD, Michael Demdorfer[#], MD, Anja Schade[¶], MD; Patrick Mueller[¶], MD; Atilla Szoelloes[¶], MD; Javier Sanchez^{*}, MD, Amin Al-Ahmad^{*}, MD, Patrick Hranitzky^{*}, MD, G. Joseph Gallinghouse^{*}, MD, Richard H. Hongo^{‡‡}, MD, Salwa Beheiry^{‡‡}, RN, Helmut Pürerfellner[#], MD, J. David Burkhardt^{*}, MD, Andrea Natale^{**‡‡§§***†††}, MD



Results

- Study Population :
 - 200 pts in the apixaban group; 200 pts in the warfarin group (N = 400) matched by age, gender, AF type and institute where ablation was performed
 - Mean Age : 65.9 ± 9.9 years
 - Male : 71.5%
 - Paroxysmal AF : 16.5%, Non-Paroxysmal AF : 83.5%
 - Hypertension : 68.5%
 - Diabetes : 19.0 %
 - Baseline Characteristics were similar between the groups

Results

- A subset of 29 patients with non paroxysmal AF underwent post ablation dMRI in the uninterrupted apixaban group **and all were negative for SCI.**

Comparison of Baseline Demographics, Clinical parameters, Medication Use between Patients on Apixaban and Warfarin

| Characteristics | Apixaban (N=200) | Warfarin (N=200) | p-value |
|----------------------------------|---------------------|---------------------|---------|
| Age (yrs) | 65.9 ± 9.9 | 65.9 ± 9.9 | 1.0 |
| Male | 143 (71.5) | 143 (71.5) | 1.0 |
| Caucasian | 183 (91.5) | 187 (93.5) | 0.45 |
| Body Mass Index | 29.4 ±6.0 | 30.1 ±6.5 | 0.25 |
| Type of AF | | | |
| Paroxysmal AF | 33 (16.5) | 33 (16.5) | 1.0 |
| Non-Paroxysmal AF | 167 (83.5) | 167 (83.5) | |
| Duration of AF (Median, IQR) | 36 (10.5, 84) | 36.0 (12.0, 96) | 0.62 |
| Heart Failure | 22 (11) | 19 (9.5) | 0.62 |
| Hypertension | 136 (68.0) | 138 (69.0) | 0.83 |
| Coronary Artery Disease | 29 (14.5) | 29 (14.5) | 1.0 |
| Dyslipidemia | 106 (53.0) | 114 (57.0) | 0.42 |
| Sleep Apnea | 22 (11.0) | 14 (7.0) | 0.16 |
| Transient Ischemic attack/Stroke | 11 (5.5) | 10 (5.0) | 0.82 |
| Diabetes | 37 (18.5) | 39 (19.5) | 0.80 |
| Left Atrial size(cm) | 4.5 ±0.8 | 4.5 ± 0.9 | 0.80 |
| LV ejection fraction (%) | 56.1 ±9.4 | 56.9 ±10.6 | 0.45 |
| Aspirin | 56(28.0) | 67 (33.5) | 0.23 |
| ACE inhibitor/ARBs | 56 (28.0) | 50 (25.0) | 0.50 |
| Digoxin | 29 (14.5) | 35 (17.5) | 0.41 |
| Statin | 93 (46.5) | 93 (46.5) | 1.00 |

Comparison of Bleeding Score and Procedural Characteristics between Patients on Apixaban and Warfarin

| Characteristics | Apixaban (N=200) | Warfarin (N=200) | p-value |
|----------------------------------------------|---------------------|---------------------|---------|
| CHADS ₂ score | 1.28 ±0.9 | 1.27 ±0.8 | 0.95 |
| CHADS ₂ score 0 | 39 (19.5) | 36(18.0) | 0.92 |
| 1 | 82 (41.0) | 85 (42.5) | |
| ≥2 | 79 (39.5) | 79 (39.5) | |
| CHA ₂ DS ₂ -VASc score | 2.28 ±1.4 | 2.30 ± 1.4 | 0.89 |
| HAS-BLED score | 1.74 ±0.98 | 1.74 ± 0.94 | 0.96 |
| Baseline INR | 1.90 ±0.5 | 2.16 ±0.5 | <0.001 |
| Presence of Scar | 136 (68.0) | 134 (67.0) | 0.82 |
| Cardioversion during the procedure | 80 (40.0) | 82 (41.0) | 0.84 |
| Additional Periprocedural Heparin Unit | 3.6 ± 1.4 | 1.6 ± 0.7 | <0.001 |
| ACT during procedure (seconds) | 342.1 ± 23.1 | 363.1 ± 26.5 | <0.001 |

- There were no differences in the usage of medications and bleeding score between the groups
- Average INR and mean ACT were higher in the warfarin group (p<0.001)
- After the bolus of heparin, patients in the apixaban group required more additional heparin units compared to the warfarin group

Composite of bleeding and embolic complications

- Overall, there was no difference in the composite of bleeding and embolic complications between the **apixaban** group [9(4.5%)] and the **warfarin** group [6(3.0%)] (**p-value = 0.43**)

Thromboembolic complications

- dMRI was negative for silent cerebral ischemia for the subset of population (n=29) in the apixaban group.
- No patients suffered Stroke/TIA.

Complications

- Total Bleeding Complication : 15 (3.8%)
 - 9(4.5%) in the apixaban group,
 - 6(3.0%) in the warfarin group, $p = 0.4$
- Major Bleeding Complications : 3 (0.8%)
 - 2(1.0%) in the apixaban group
 - 1(0.5%) in the warfarin group, $p=1.0$
- Minor Bleeding Complications : 12 (3.0%)
 - 7(3.5%) in the apixaban group
 - 5(2.5%) in the warfarin group, $p=0.6$

Complications

■ Major Bleeding Complications

- All complications were Pericardial effusion (PE) with tamponade (0.8%)
- 1 early PE in both the groups, 1 delayed PE in the apixaban group
- Managed by percutaneous pericardial drainage
- None of the patients required surgical drainage

■ Minor Bleeding Complications

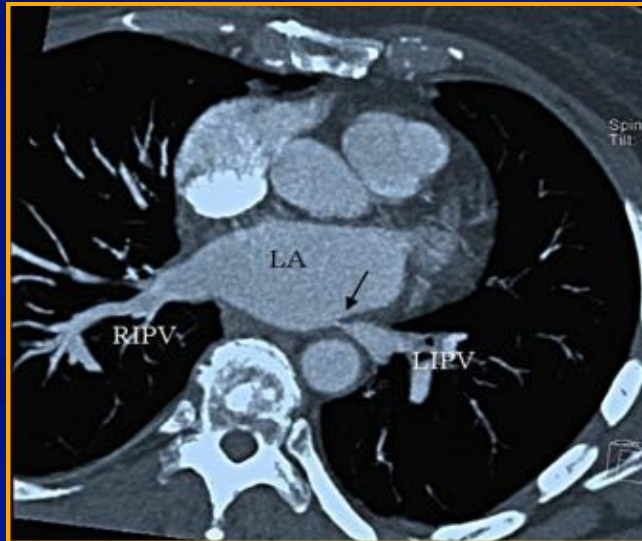
- Groin Hematoma(1.3%)
 - 3 (1.5%) patients in the apixaban group
 - 2 (1.0%) patients in the warfarin group, $p=1.0$
- Pericardial Effusion without Tamponade (1.3%)
 - 3 (1.5%) patients in the apixaban group
 - 2 (1.0%) patients in the warfarin group, $p=1.0$
- GI bleeding :1 (0.5 %) patient in the apixaban group
- Hematuria : 1 (0.5%) patient in the warfarin group

■ Thromboembolic Complication

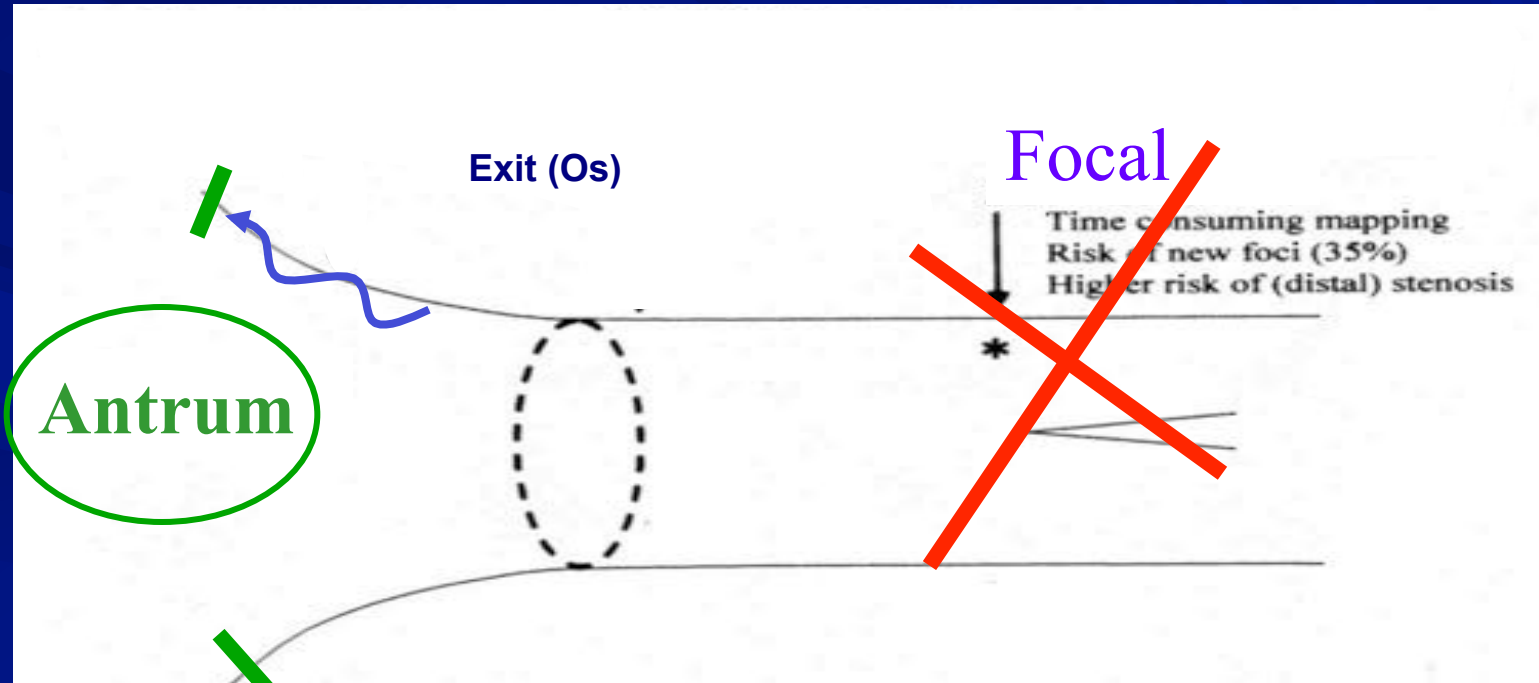
- **Stroke/TIA** : No patient had thromboembolic complications

PV stenosis

- Overall incidence: 1-29%
- Severe PV stenosis: 1.6%and decreasing
- Depends on ablation approach



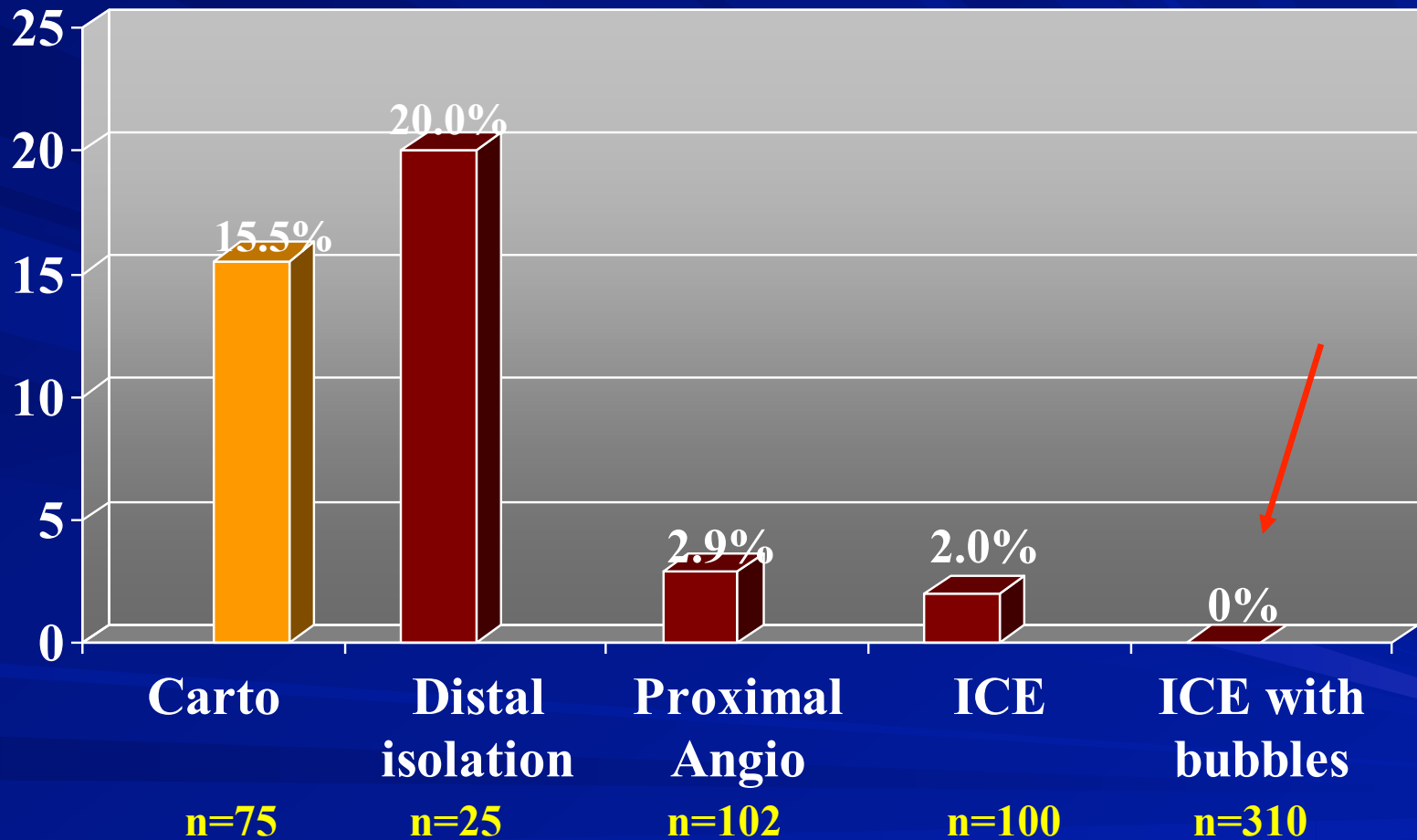
AF Catheter Ablation Strategies

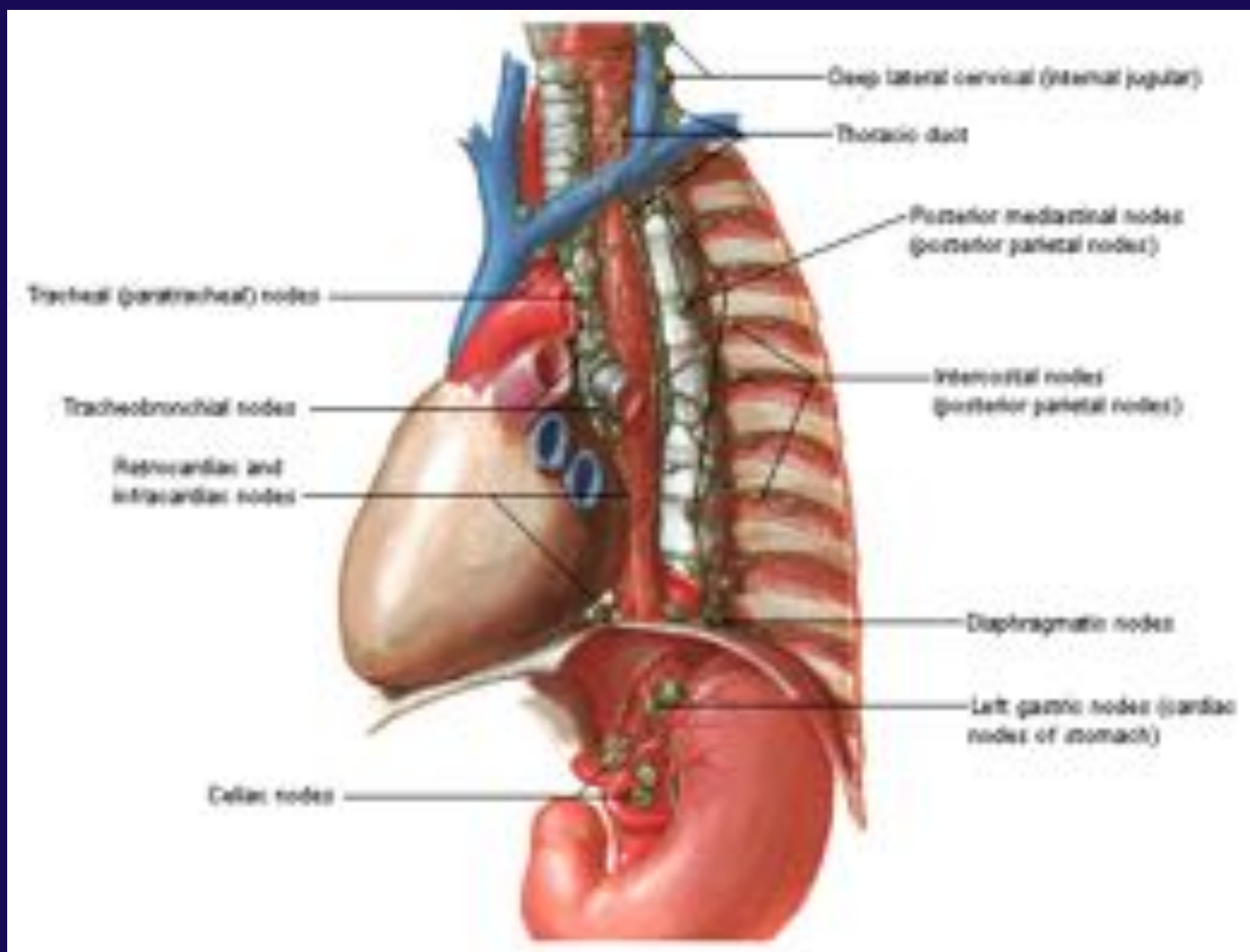


More Proximal ablation: The PV **Antrum**

Severe PV Stenosis

■ Circular mapping ■ Carto

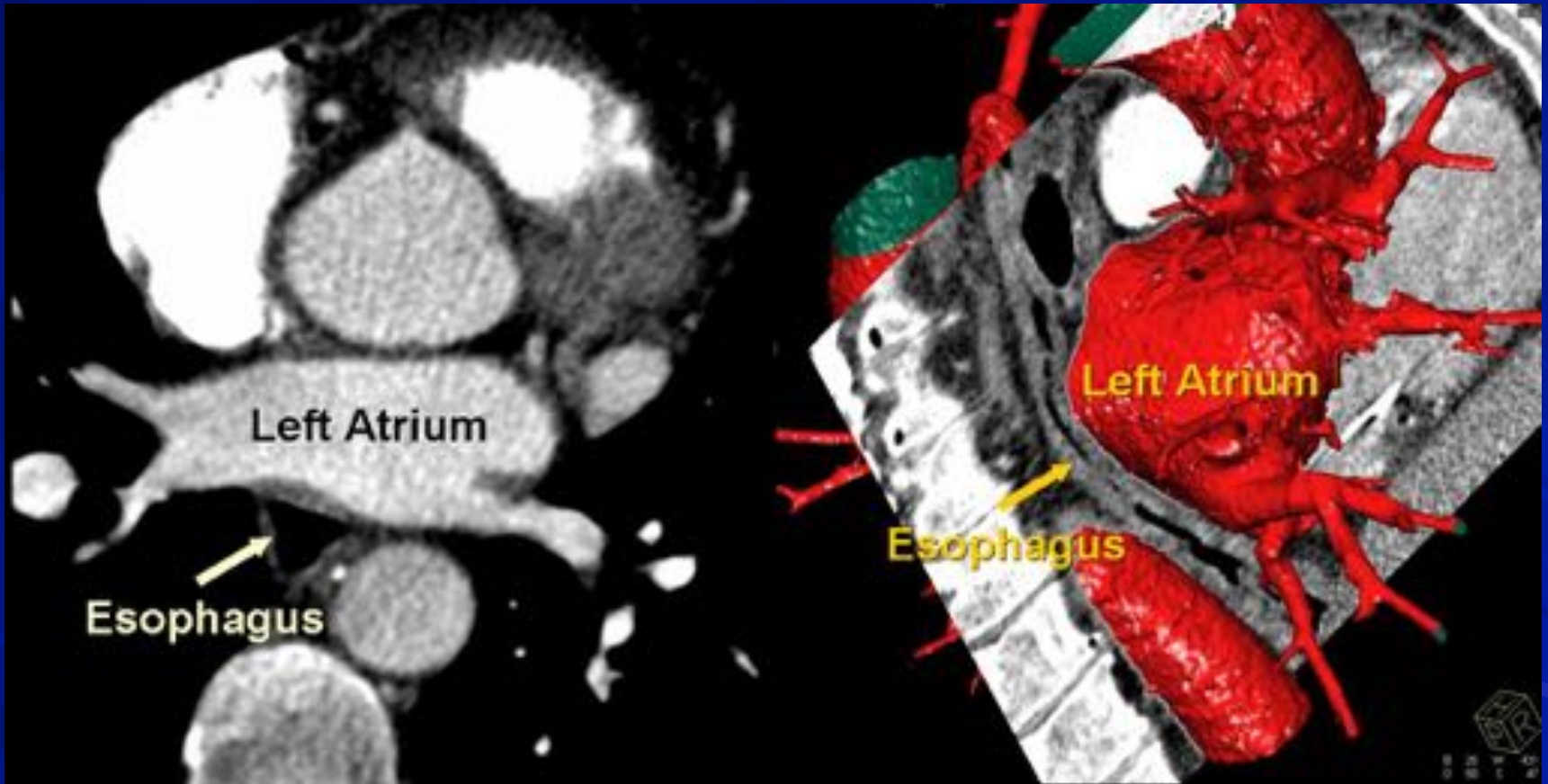




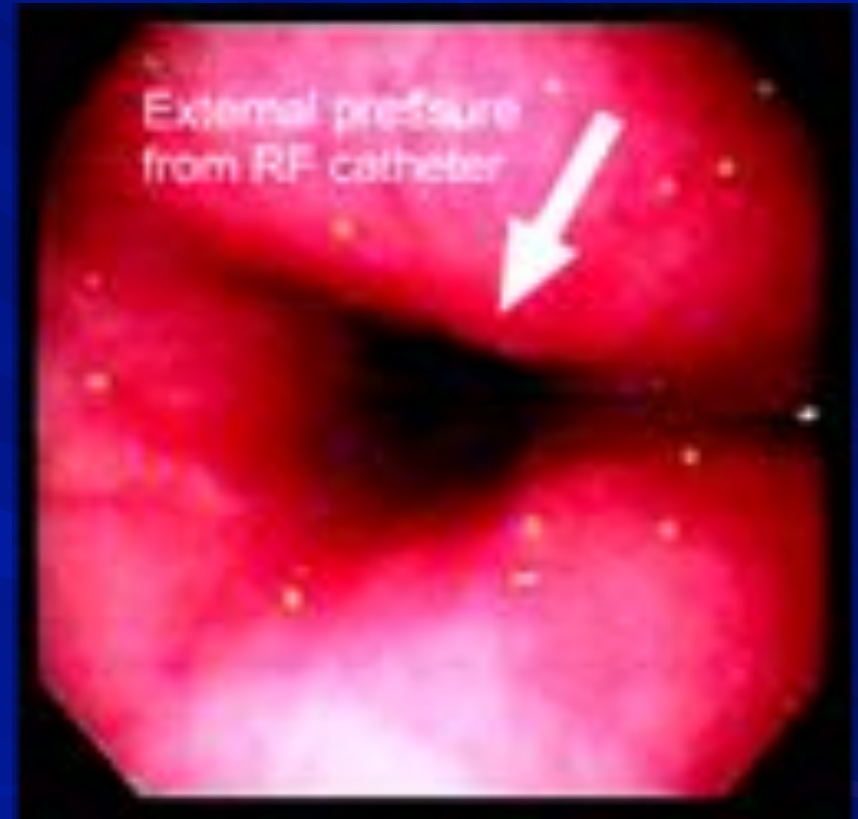
Esophageal Injury

- The esophagus is close to the posterior LA wall.
- The posterior LA wall is thin
- The esophagus has a variable course

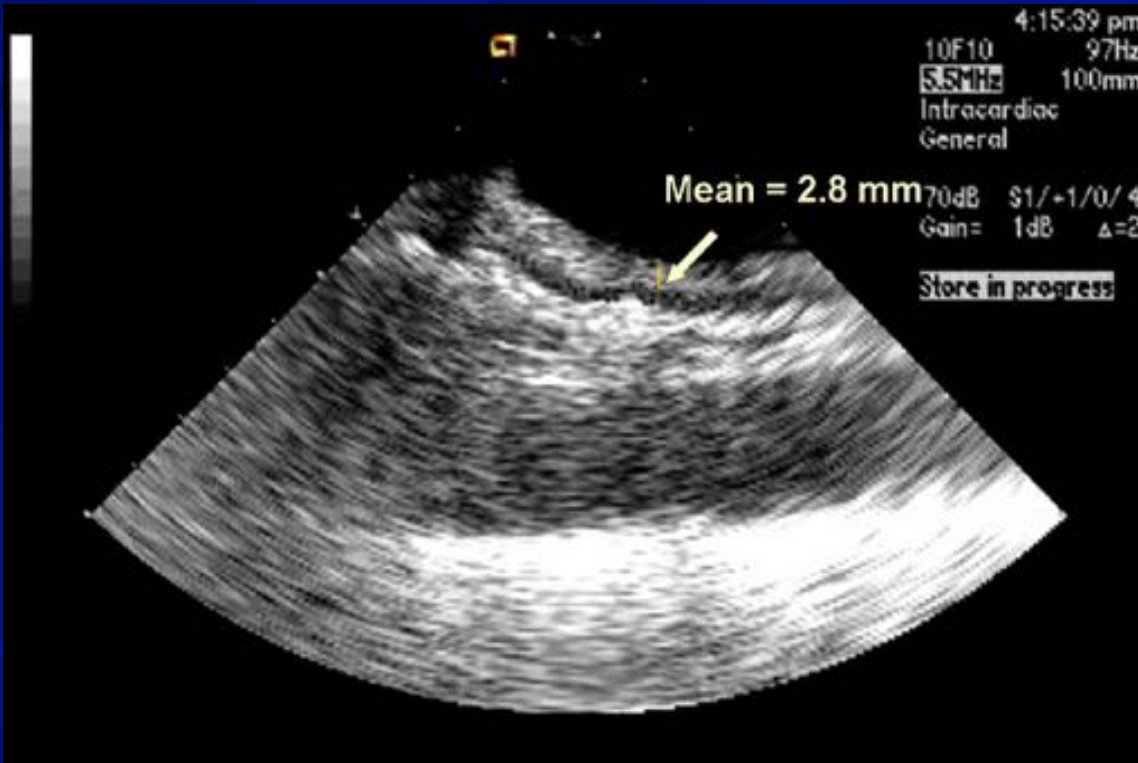
LA- Esophagus Proximity: Anatomy



Posterior LA ablation: Impact on Esophageal Lumen



Posterior LA Wall Thickness by ICE



The mean LA wall thickness as measured by ICE
2.8mm +/- 0.9mm
(1.9mm – 4.0mm)

Esophageal Course

| | Right PVs | Mid Posterior Wall | Left PVs |
|--------------------------|----------------------|---------------------------|---------------------|
| Esophageal Course | 28.4% (21/81) | 33% (27/81) | 38.3%(31/81) |

Atrial Esophageal Fistula

- Incidence 0.01% - underestimated due to underreporting
- Mechanism – thermal injury to anterior esophageal wall following ablation along posterior LA wall
 - Once injured, fistula development preceded by inflammatory response leading to atrial and esophageal tissue necrosis

Contributing Factors

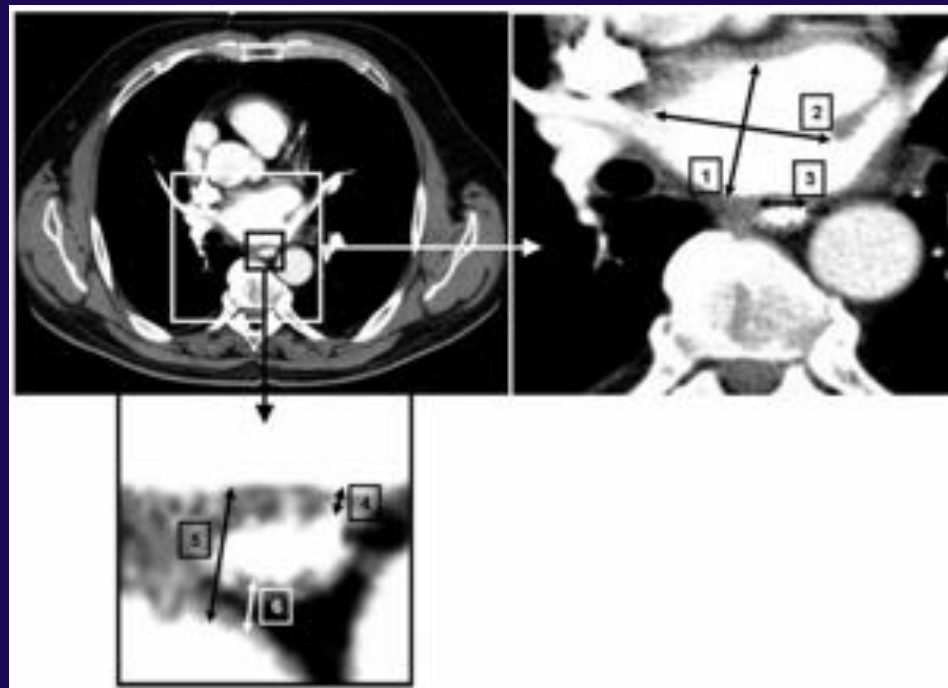
- Power $>50\text{W}$ (8mm) or $>35\text{W}$ (irrigated tip)
- Long Energy application
- Small Atrial Size
- Use of Large Tip Catheters ???
- Overlapping lesions in posterior LA ???
- High contact pressure

Identification of a high-risk population for esophageal injury during radiofrequency catheter ablation of atrial fibrillation: Procedural and anatomical considerations

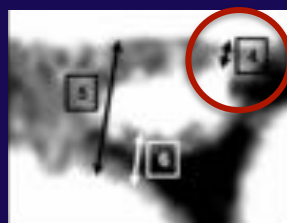
Martin Martinek, MD,^{*} Christian Meyer, MD,^{*} Said Hassanein, MD,^{*} Josef Aichinger, MD,^{*} Gabor Bencsik, MD,[†] Rainer Schoefl, MD,[‡] Gernot Boehm, MD,[§] Hans-Joachim Nesser, MD,^{*} Helmut Purerfellner, MD^{*}



Figure 1 Endoscopic appearance of esophageal lesions. A: Necrotic ulceration. B: Erythema.



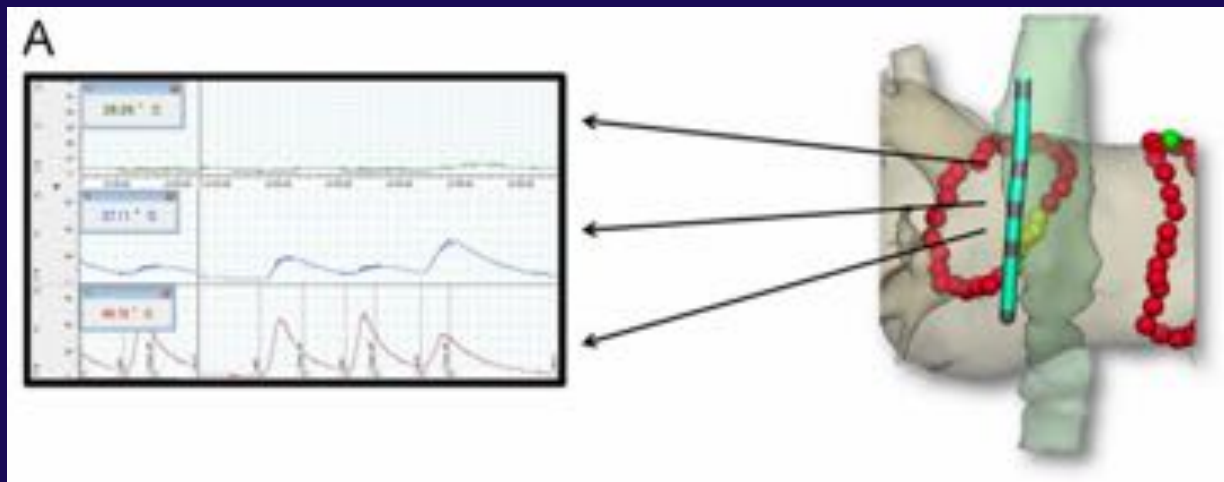
| | Esophageal ulceration | | P value |
|-------------------------------------------------------------|-----------------------|-----------------|---------|
| | No | Yes | |
| Type of atrial fibrillation | | | |
| Paroxysmal | 171 | 1 | .023 |
| Persistent | 90 | 5 | |
| Sedation/anesthesia | | | |
| Deep sedation | 224 | 5 | .863 |
| General anesthesia | 37 | 1 | |
| Additional ablation sites | | | |
| Roof line | 108 of 261 | 6 of 6 | .006 |
| Left atrial isthmus line | 45 of 261 | 4 of 6 | .011 |
| Coronary sinus | 61 of 261 | 5 of 6 | .004 |
| Inferior line | 26 of 261 | 2 of 6 | .115 |
| CFAE ablation | 40 of 261 | 1 of 6 | .636 |
| Radiofrequency energy (Ws) delivered | | | |
| On posterior wall | 24,739 ± 9,374 | 22,180 ± 17,360 | .648 |
| Total | 71,440 ± 22,928 | 61,583 ± 41,960 | .467 |
| 1 LA anteroposterior diameter | 35.0 ± 6.0 | 43.2 ± 9.1 | .001 |
| 2 LA transverse diameter | 49.8 ± 6.4 | 58.3 ± 5.9 | .001 |
| 3 LA to esophagus contact width | 17.2 ± 5.2 | 22.5 ± 3.1 | .013 |
| 4 LA to esophagus distance | 2.5 ± 0.7 | 2.0 ± 0.3 | .0001 |
| 5 LA to spine distance | 13.5 ± 5.1 | 9.2 ± 1.6 | .038 |
| 6 Esophagus spine distance | 6.9 ± 4.1 | 5.0 ± 1.0 | .255 |
| 7 Cranio-caudal LA - esophagus contact (<5 mm LA* to spine) | 60 ± 13 | 64 ± 24 | .724 |



| | Esophageal ulceration | |
|-------------------------------------|-----------------------|--------------|
| | Standard coefficient | P value |
| Persistent atrial fibrillation | 0.145 | .8033 |
| Roof line | 0.195 | .2663 |
| Left atrial isthmus line | 0.258 | .0789 |
| Coronary sinus | 0.253 | .0729 |
| Left atrium to esophagus distance | -0.159 | .0176 |
| Significance (analysis of variance) | | .001 |

Impact of esophageal temperature monitoring guided atrial fibrillation ablation on preventing asymptomatic excessive transmural injury

Kunihiko Kiuchi, MD, FHRS^{a,d}, Katsunori Okajima, MD^a, Akira Shimane, MD^a, Gaku Kanda, MD^a, Kiminobu Yokoi, MD^a, Jin Teranishi, MD^a, Kousuke Aoki, MD^a, Misato Chimura, MD^a, Takayoshi Toba, MD^a, Shogo Oishi, MD^a, Takahiro Sawada, MD^d, Yasue Tsukishiro, MD^a, Tetsuuri Onishi, MD^a, Seiichi Kobayashi, MD^a, Yasuyo Taniguchi, MD^a, Shinichiro Yamada, MD^a, Yoshinori Yasaka, MD^a, Hiroya Kawai, MD^a, Akihiro Yoshida, MD^b, Koji Fukuzawa, MD^b, Mitsuaki Itoh, MD^b, Kimitake Imamura, MD^b, Ryudo Fujiwara, MD^b, Atsushi Suzuki, MD^b, Tomoyuki Nakanishi, MD^b, Soichiro Yamashita, MD^b, Ken-ichi Hirata, MD^b, Hiroshi Tada, MD, FHRS^c, Hiro Yamasaki, MD^d, Yoshihisa Naruse, MD^d, Miyako Igarashi, MD^d, Kazutaka Aonuma, MD^d



Incidence of ETI and AF recurrence in the 2 patient groups.

| | ETM group | Non-ETM group | <i>p</i> Value |
|------------------------------------|-----------|---------------|----------------|
| ETI (n, %) | 2 (3) | 9 (11) | 0.06 |
| Esophageal injury (n, %) | 0 (0) | 6 (7,5) | 0.03 |
| Periesophageal nerve injury (n, %) | 2 (3) | 3 (4) | 1.00 |
| AF recurrence (n, %) | 20 (25) | 19 (24) | 1.00 |

Esophageal Capsule Endoscopy After Radiofrequency Catheter Ablation for Atrial Fibrillation

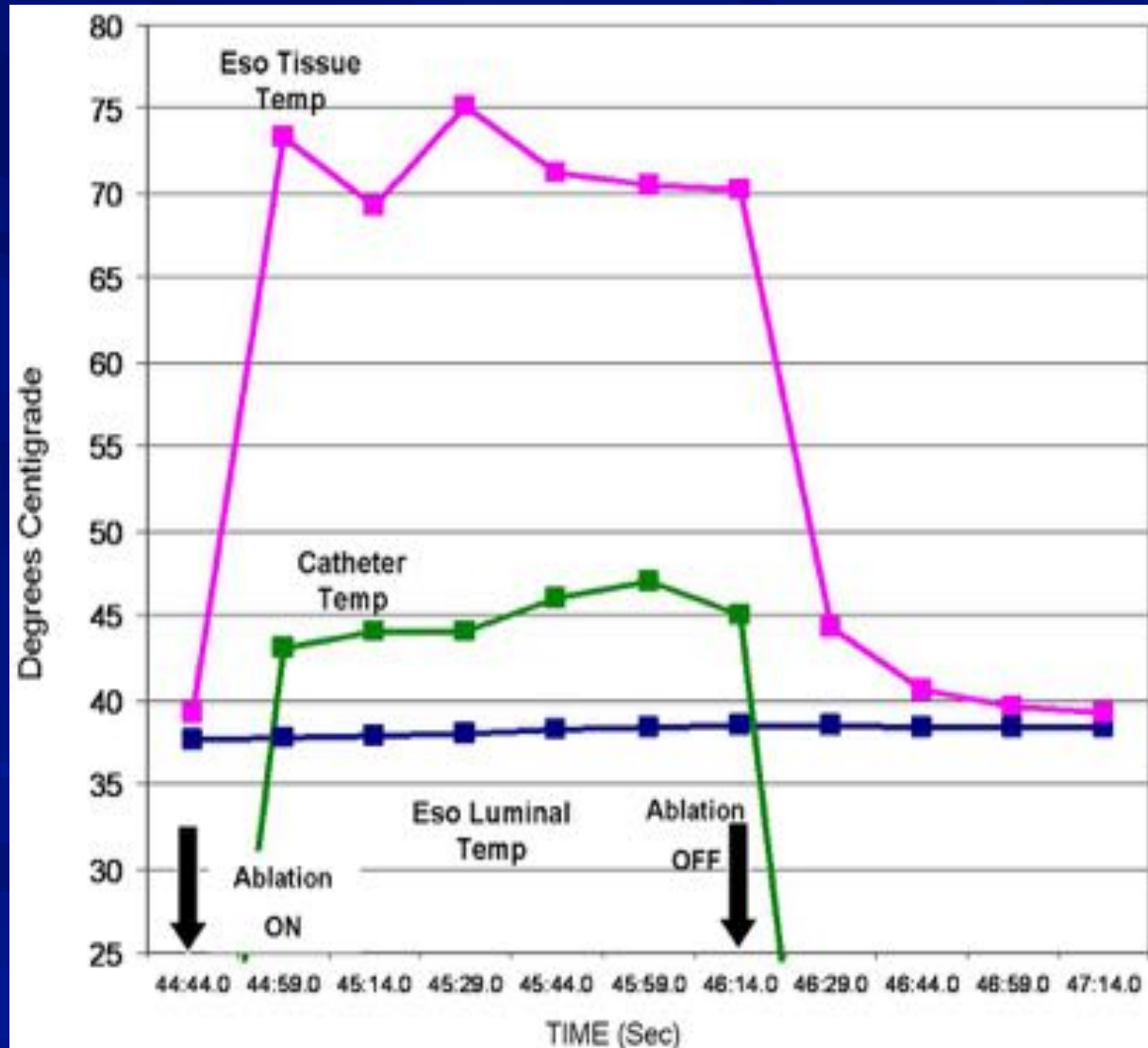
Documented Higher Risk of Luminal Esophageal Damage With General Anesthesia as Compared With Conscious Sedation

Luigi Di Biase, MD; Luis Carlos Saenz, MD; David J. Burkhardt, MD; Miguel Vacca, MD; Claude S. Elayi, MD; Conor D. Barrett, MD; Rodney Horton, MD; Rong Bai, MD; Alan Siu, MD; Tamer S. Fahmy, MD; Dimpri Patel, DO; Luciana Armaganijan, MD; Chia Tung Wu, MD; Sonne Kai, MD; Ching Keong Ching, MD; Karen Phillips, MD; Robert A. Schweikert, MD; Jennifer E. Cummings, MD; Mauricio Arruda, MD; Walid I. Saliba, MD; Milan Dodig, MD; Andrea Natale, MD

| | Group 1: General Anesthesia (n=25) | Group 2: Conscious Sedation (n=25) | P Value |
|------------------------------------------------|------------------------------------------|------------------------------------------|---------|
| Maximum esophageal temperature | 40.6±1°C | 39.6±0.8°C | <0.003 |
| Time to baseline temperature recovery, seconds | 29±3 | 18±2 | <0.001 |
| Time to peak temperature, seconds | 9±7 | 21±9 | <0.001 |
| Esophageal tissue damage, n (%) | 12 (48) | 1 (4) | <0.001 |



Is luminal esophageal temperature the best



- Animal data clearly demonstrate that external esophageal tissue temperatures exceed luminal temperatures by far
- However, tissue temperature monitoring in humans is not currently feasible

Esophageal Luminal Temperature Underestimates Esophageal Tissue Temperature During Radiofrequency Ablation Within the Canine Left Atrium: Comparison Between 8 mm Tip and Open Irrigation Catheters

JENNIFER E. CUMMINGS, M.D., CONOR D. BARRETT, M.R.C.P.,
KENNETH N. LITWAK, D.V.M., Ph.D., LUIGI DI BIASE, M.D., PUNAM CHOWDHURY, M.D.,
SEIL OH, M.D., CHI KEONG CHING, M.D., WALID I. SALIBA, M.D.,
ROBERT A. SCHWEIKERT, M.D., J. DAVID BURKHARDT, M.D., SHARI DE MARCO, R.V.T.,
LUCIANA ARMAGANJAN, M.D., and ANDREA NATALE, M.D.*†‡

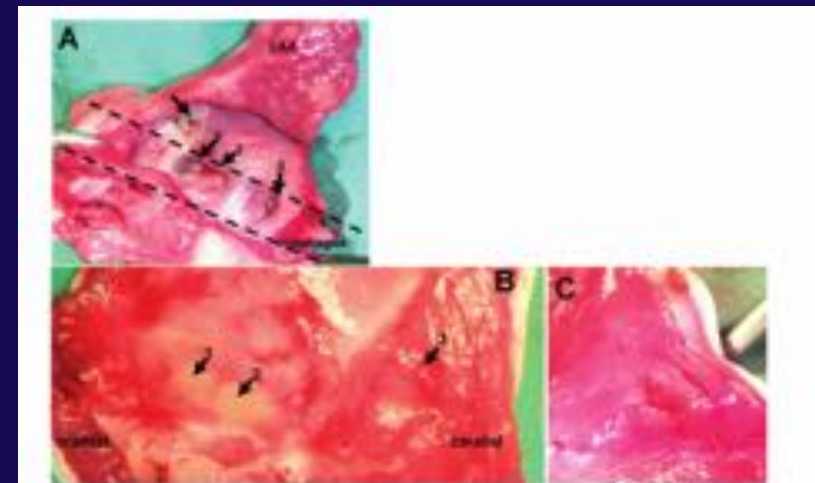
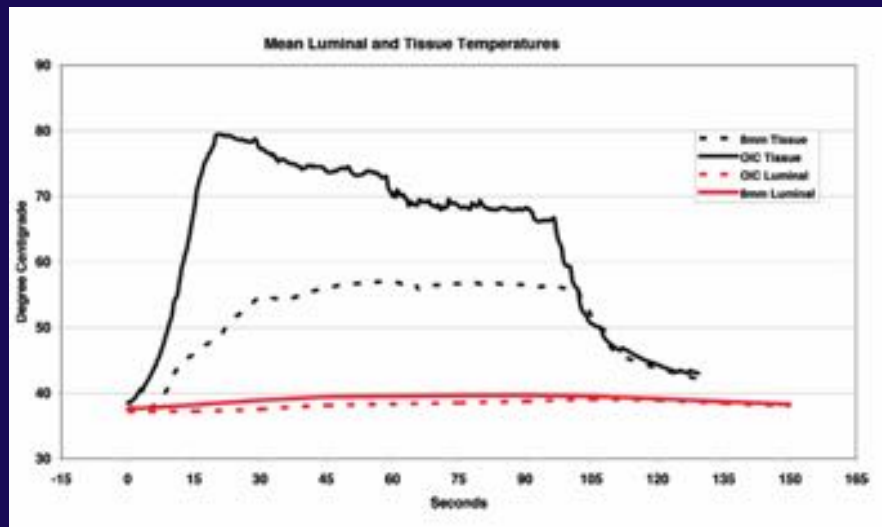
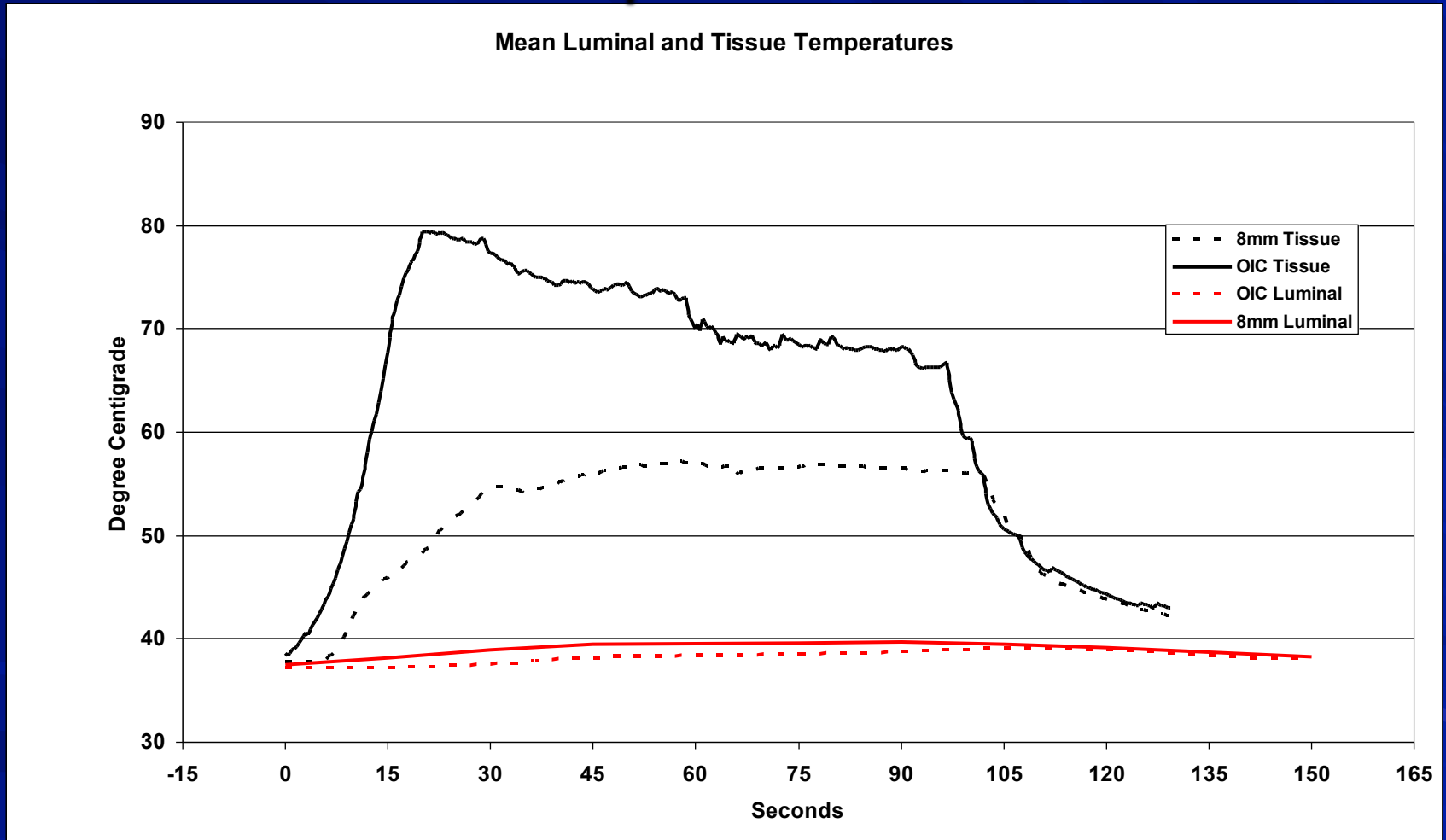


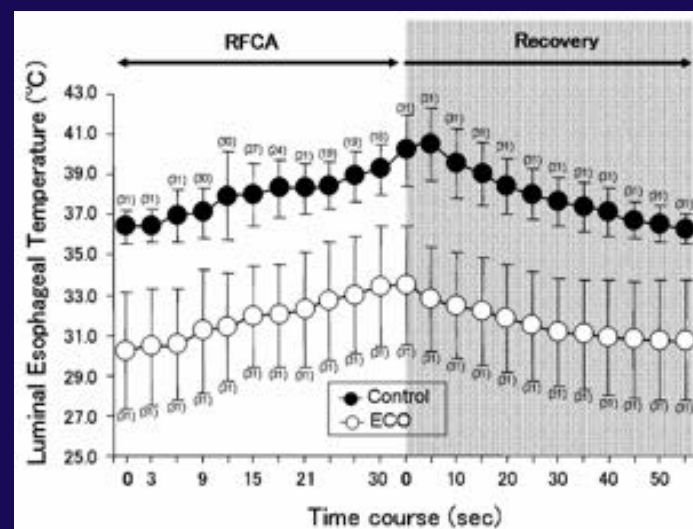
Figure 3. The three panels are a representative example of esophageal injury during lesions delivered by an open irrigated catheter. Panel A demonstrates the endocardial lesions sites, Panel B demonstrates the same lesions on the epicardial surface, and Panel C demonstrates the associated external esophageal injury associated with these lesions.

Time Course Of Luminal And Tissue Temperatures



Atrial Fibrillation Ablation with Esophageal Cooling with a Cooled Water-Irrigated Intraesophageal Balloon: A Pilot Study

TAKESHI TSUCHIYA, M.D.,* KEIICHI ASHIKAGA, M.D.,† SUSUMU NAKAGAWA, M.D.,‡
KIYOSHI HAYASHIDA, M.D.,§ and HIROSHI KUGIMIYA, M.D.¶



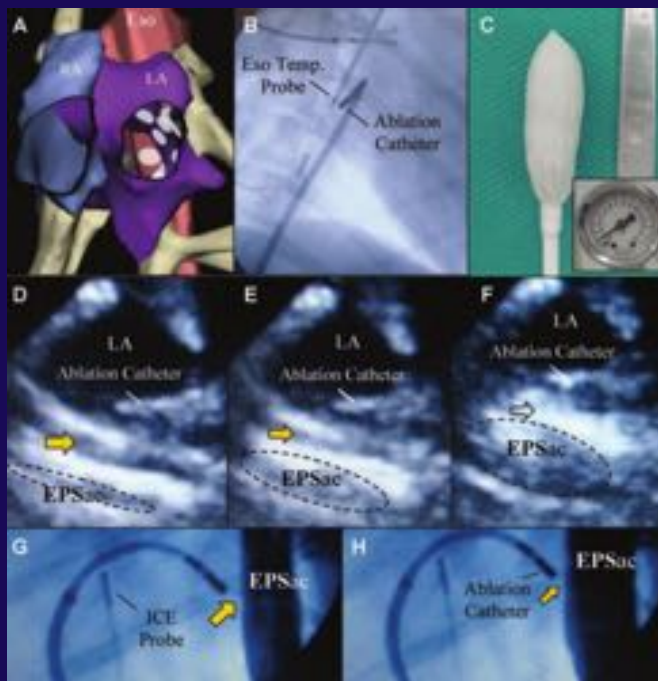
Feasibility and Safety of Using an Esophageal Protective System to Eliminate Esophageal Thermal Injury: Implications on Atrial-Esophageal Fistula Following AF Ablation

MAURICIO S. ARRUDA, M.D.,* LUCIANA ARMAGANIJAN, M.D.,†‡ LUIGI DI BIASE, M.D.,‡,¶,§
 RASSOLL RASHIDI, B.M.E.,§ and ANDREA NATALE, M.D.‡

From the *Case Western Reserve University School of Medicine, Cleveland, Ohio, USA; †Hamilton Health Sciences, Hamilton, Ontario, Canada; ‡Texas Cardiac Arrhythmias Institute, Austin, Texas, USA; ¶Department of Cardiology, University of Foggia, Foggia, Italy; and §RossHart Technologies Inc., Cleveland, Ohio, USA

Effects of Circulating EPSac Fluid Temperature on Esophageal Thermal Injury

| RF Power | Duration 30 Seconds RF (N) | Circulating EPSac Fluid Temperature | | | | | | | |
|----------|----------------------------------|-------------------------------------|---------------|-----------------|---------------|-----------------|---------------|-----------------|---------------|
| | | 25°C | | 15°C | | 10°C | | 5°C | |
| | | Mean IT (°C) | ESO Injury | Mean IT (°C) | ESO Injury | Mean IT (°C) | ESO Injury | Mean IT (°C) | ESO Injury |
| 25 W | 12 | 65 | Yes | 60 | Yes | 49 | No | 45 | No |
| 35 W | 12 | 64 | Yes | 62 | Yes | 52 | No | 52 | No |
| 45 W | 12 | 67 | Yes | 62 | Yes | 55 | No | 55 | No |

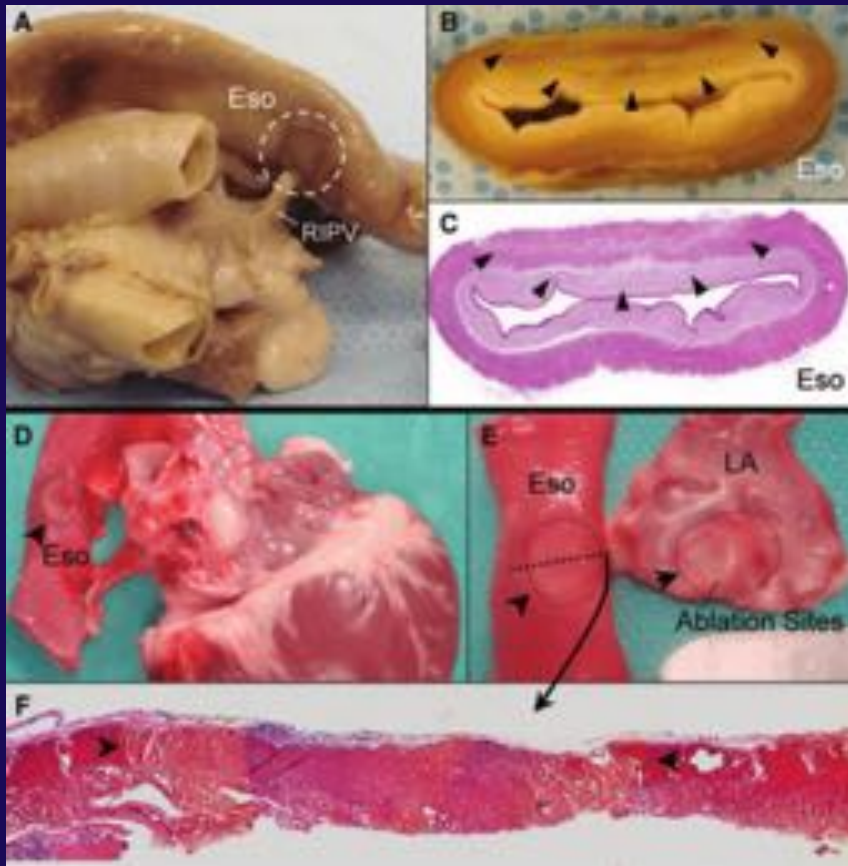


No injury with circulating fluid temperature of 10 or 5 °C



2 dogs

- 1 control
- 1 ESO 25 °C (room temp)
- 2 ESO 10 °C
- 2 ESO 5 °C ← 1 with esophagus displaced toward LA



Transmural lesions

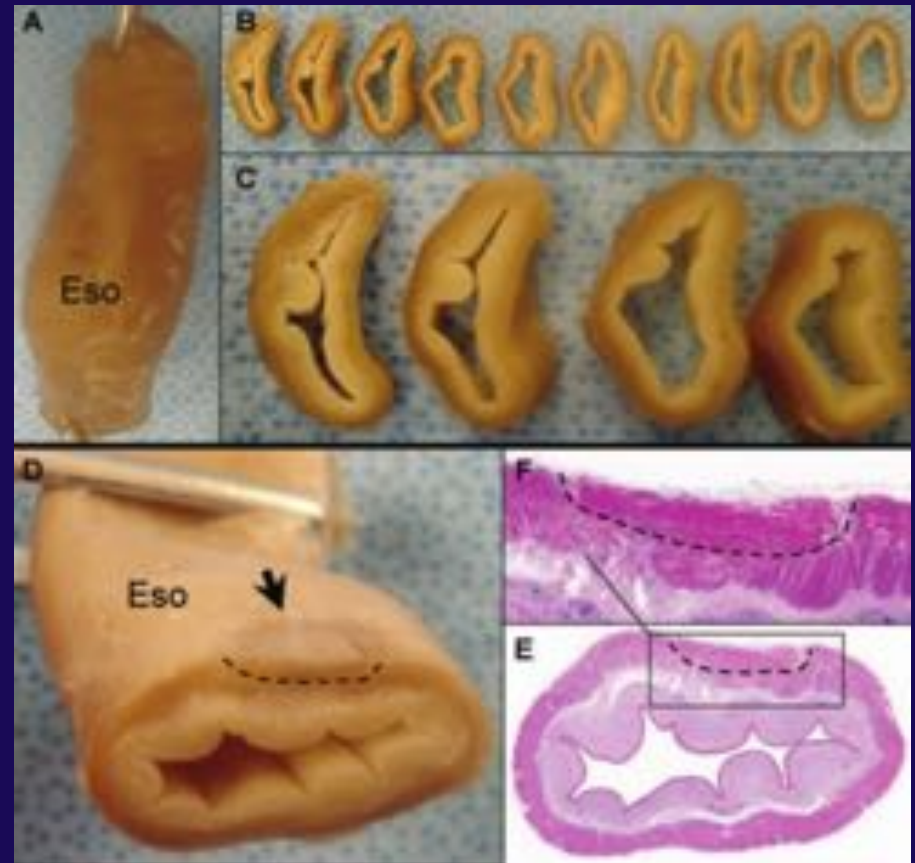
- Control
- ESO 25 °C

No lesion

- ESO 5° and 10 °C

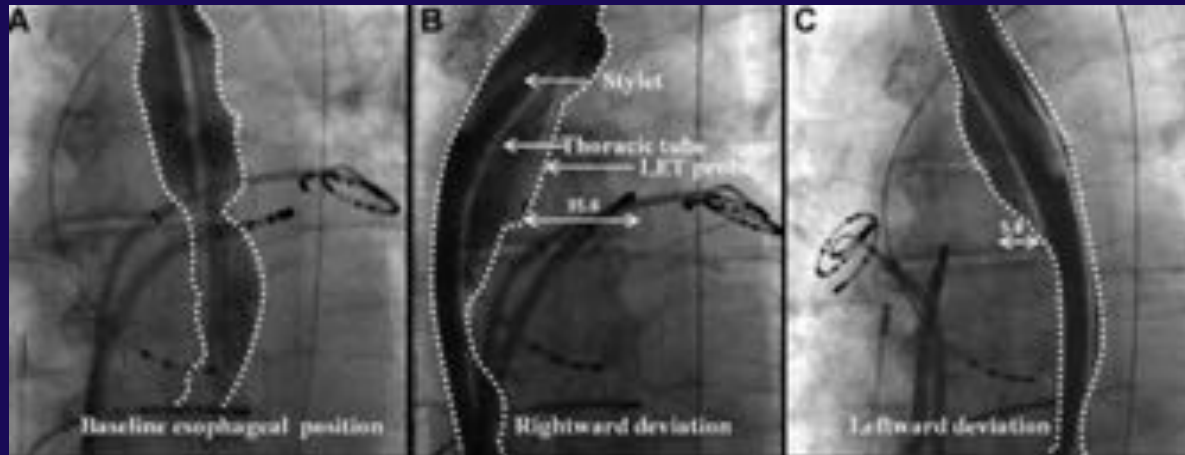
Muscularis lesion

- ESO 5 °C and 10 °C when esophagus displaced toward LA



Mechanical Esophageal Displacement During Catheter Ablation for Atrial Fibrillation

JACOB S. KORUTH, M.D., VIVEK Y. REDDY, M.D., MARC A. MILLER, M.D.,
KALPESH K. PATEL, M.D., JAMES O. COFFEY, M.D., AVI FISCHER, M.D.,
J. ANTHONY GOMES, M.D., SRINIVAS DUKKIPATI, M.D., ANDRE D'AVILA, M.D.,
and ALEXANDER MITTNACHT, M.D.



| | |
|--------------------------------------------------------------|------------|
| Number of pts with temp rises $> 38.5^{\circ}$ (n = 20) | 3/20 (15%) |
| Number of pts with temp rises $> 40^{\circ}$ | 0/20 (0%) |
| Mean number of lesions/pt with temp rise $> 38.5^{\circ}$ | 2 |

| | |
|-----------------------------------------------------------|----------------|
| Number of pts with temp rises $> 38.5^{\circ}$ | 18/20 (90%) |
| Mean number of lesions/pt with temp rise $> 38.5^{\circ}$ | 6.15 ± 4.3 |

Control group

Outcomes of Atrioesophageal Fistula Following Catheter Ablation of Atrial Fibrillation Treated with Surgical Repair versus Esophageal Stenting

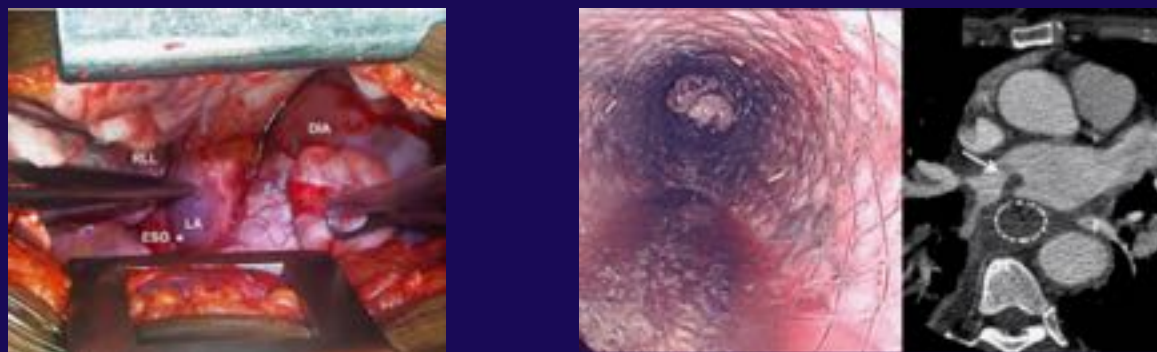
SANGHAMITRA MOHANTY, M.D., M.S.,* ,† PASQUALE SANTANGELI, M.D.,* ,‡
 PRASANT MOHANTY, M.B.B.S., M.P.H.,* LUIGI DI BIASE, M.D., Ph.D.,* ,‡,§,¶
 CHINTAN TRIVEDI, M.D., M.P.H.,* RONG BAI, M.D.,* ,# RODNEY HORTON, M.D.,*
 J. DAVID BURKHARDT, M.D.,* JAVIER E. SANCHEZ, M.D.,* JASON ZAGRODZKY, M.D.,*
 SHANE BAILEY, M.D.,* JOSEPH G. GALLINGHOUSE, M.D.,* PATRICK M. HRANITZKY,
 M.D.,* ALBERT Y. SUN, M.D.,|| RICHARD HONGO, M.D.,** SALWA BEHEIRY, R.N.,** and
 ANDREA NATALE, M.D.,* ,§,**,††,‡‡,§§

| Case # | Age | Sex | AF Type | Temp. (°C) | W (Watts) | ES | Time | Complications | Treatment | Outcome |
|--------|-----|-----|---------|------------|-----------|-----|---------|---------------------------------------------------------------------------------------------|-----------------|----------|
| 5 | 62 | F | PAF | 39 °C | 25 W | No | 6 weeks | Chest pain, stroke/TIA, leukocytosis | Stent | Deceased |
| 6 | 51 | M | LSPAF | 38 °C | 35 W | Yes | 4 weeks | Stroke/TIA, systemic embolism, chest pain, GI hemorrhage, leukocytosis | Surgical repair | Alive |
| 7 | 59 | M | LSPAF | 39 °C | 30 W | Yes | 2 weeks | Fever, chest pain, sepsis, stroke/TIA, leukocytosis | Surgical repair | Alive |
| 8 | 42 | M | PerAF | 40 °C | 36 W | Yes | 3 weeks | Fever, rigor, chest pain, sepsis, gastrointestinal bleeding, systemic embolism, stroke/TIA | Surgical repair | Alive |
| 9 | 56 | M | PAF | 39 °C | 25 W | Yes | 4 weeks | Fever, chest pain, dysphagia, confusion, leukocytosis, postprandial TIA, multiple petechiae | Surgical repair | Alive |

Esoph.: esophageal; LAPW = left atrial posterior wall; LSPAF = longstanding persistent AF; PAF = paroxysmal atrial fibrillation; PerAF = persistent atrial fibrillation; PPI = proton pump inhibitors; NA = not available; Temp.: temperature; TIA = transient ischemic attack; W = Watts.
 *Only epicardial surgical ablation performed.

Clinical outcomes after repair of left atrial esophageal fistulas occurring after atrial fibrillation ablation procedures

Sheldon M. Singh, MD,^{*} Andre d'Avila, MD, PhD,[†] Steve K. Singh, MD, MSc,[‡] Paul Stelzer, MD,[§] Eduardo B. Saad, MD, FHRS,^{||} Allan Skanes, MD, FHRS,[¶] Arash Aryana, MD, FHRS,[#] Jason S. Chinitz, MD,[†] Robert Kulina, MD,[†] Marc A. Miller, MD,[†] Vivek Y. Reddy, MD[†]



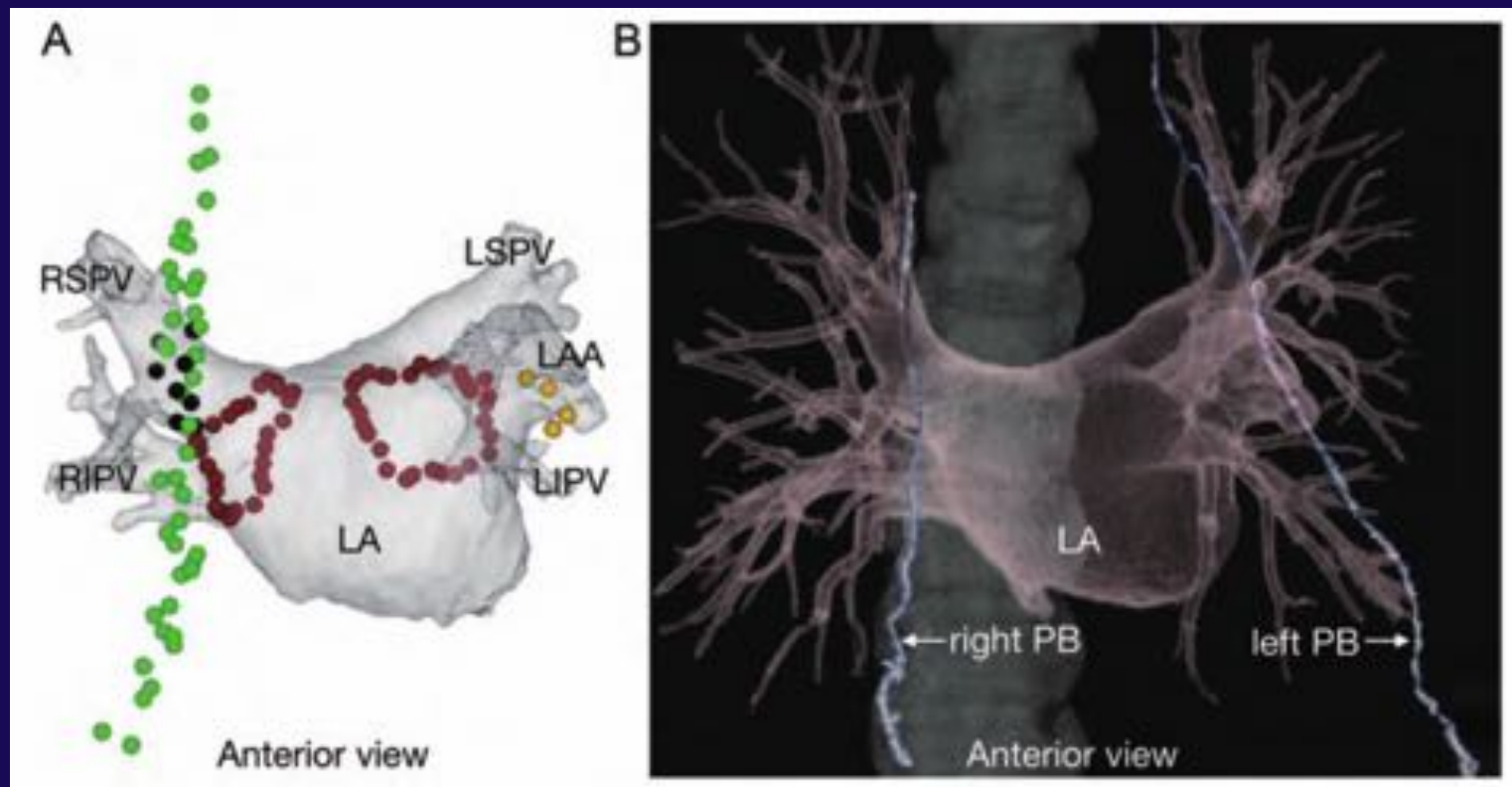
The mean age of all cases reported was 55 ± 13 years, and 75% were men. Cases presented 30 ± 12 days postablation. Overall, 55% (16 of 29) of the patients receiving an intervention for LAEF died: the case fatality rate was 41% (9 of 22) for surgical repair and 100% for esophageal stent.

Phrenic Nerve Injury

- Incidence: 0.48%
- Right Phrenic Nerve most commonly involved (80%)
- Associated with symptoms in 69% of affected patients
- Recovery in 81% (Partial 17%)
- Mean time to recovery 7 ± 7 months

Three-dimensional imaging and mapping of the right and left phrenic nerves: relevance to interventional cardiovascular therapy

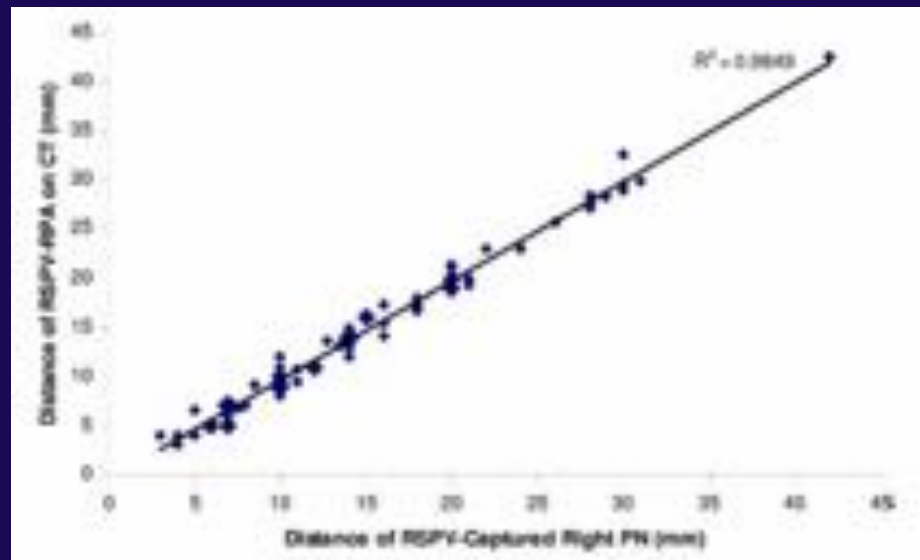
Kotaro Fukumoto^{1*}, Seiji Takatsuki¹, Masahiro Jinzaki², Minoru Yamada³, Kojiro Tanimoto¹, Nobuhiro Nishiyama¹, Yoshiyasu Aizawa¹, Yoko Hagiwara¹, Yukiko Fukuda¹, Takehiro Kimura¹, Shunichiro Miyoshi¹, Sachio Kuribayashi², and Keiichi Fukuda¹



Pace-mapping predicts PN location

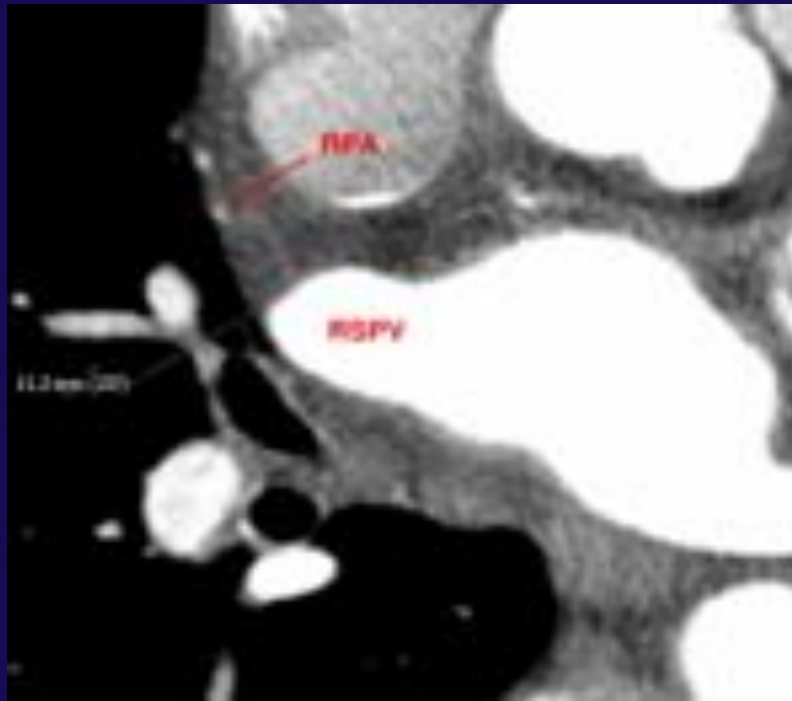
Locating the right phrenic nerve by imaging the right pericardiophrenic artery with computerized tomographic angiography: Implications for balloon-based procedures

Rodney Horton, MD, FACC,*[†] Luigi Di Biase, MD,*^{†‡} Vivek Reddy, MD,[§] Petr Neuzil, MD,^{||} Prasant Mohanty, MBBS, MPH,* Javier Sanchez, MD,* Tuan Nguyen, MD,* Sanghamitra Mohanty, MD,* G. Joseph Gallinghouse, MD,* Shane M. Bailey, MD,* Jason D. Zagrodzky, MD,* J. David Burkhardt, MD,* Andrea Natale, MD, FACC, FHRS*^{††¶¶}



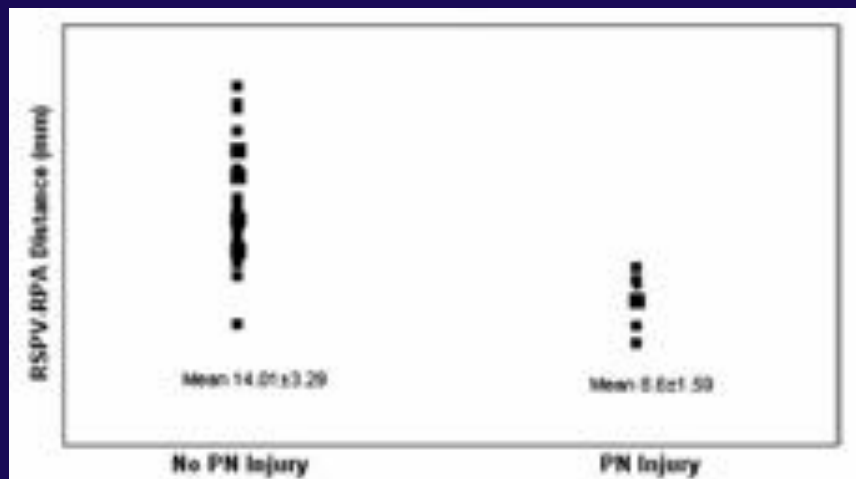
When measured in AP, distance RSPV-RPA on CT* is identical to the distance of RSPV-PN capture on fluoroscopy

*64-slices MDCT coronary artery protocol



3 groups, based on RSPV-RPA distance

- short ≤ 10 mm
- medium 10.1 to 20 mm
- long > 20 mm

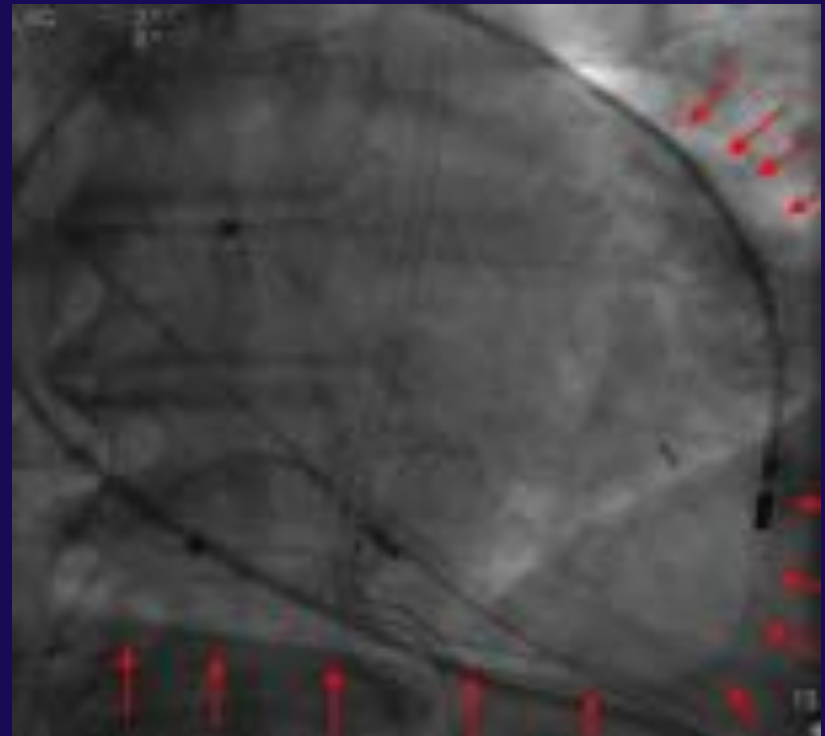


37 balloon-ablation procedures

- 7 patients with short RSPV-RPA
- 6/7 had PN injury

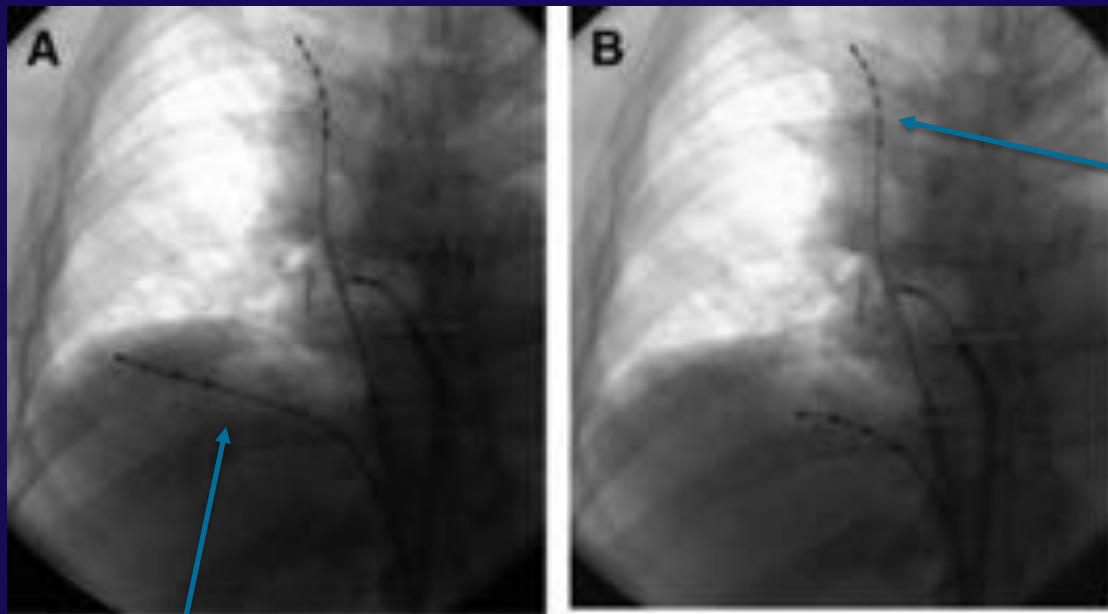
Prevention of phrenic nerve injury during epicardial ablation: Comparison of methods for separating the phrenic nerve from the epicardial surface

Luigi Di Biase, MD,*[†] J. David Burkhardt, MD,* Gemma Pelargonio, MD,[¶] Antonio Dello Russo, MD,[¶]
Michela Casella, MD,[¶] Pietro Santarelli, MD,[¶] Rodney Horton, MD,* Javier Sanchez, MD,*
Joseph G. Gallinghouse, MD,* Amin AL-Ahmad, MD,[‡] Paul Wang, MD,[‡] Jennifer E. Cummings, MD,[§]
Robert A. Schweikert, MD,[§] Andrea Natale, MD, FHRP*^{†§}



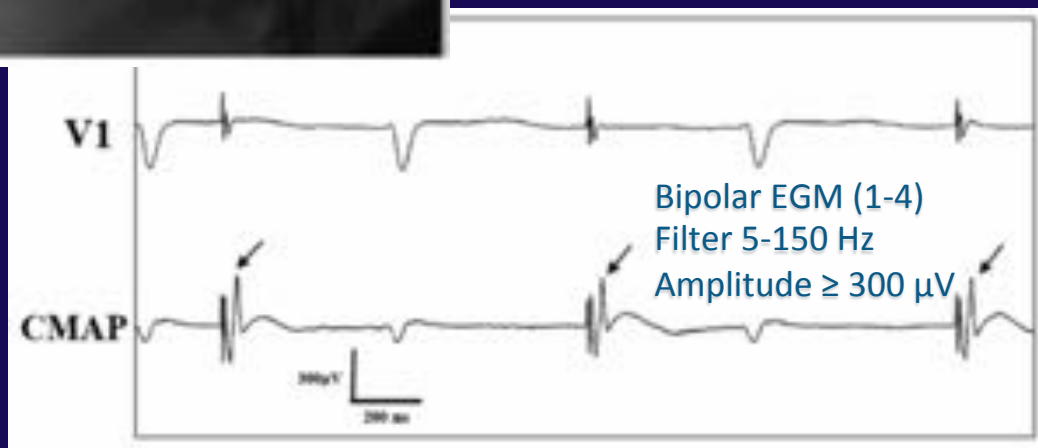
Novel Electromyographic Monitoring Technique for Prevention of Right Phrenic Nerve Palsy During Cryoballoon Ablation

Frédéric Franceschi, MD, PhD; Linda Koutbi, MD; Julien Mancini, MD, PhD; Shahram Attarian, MD, PhD; Sébastien Prevôt, MD; Jean-Claude Deharo, MD



Hexapolar in the SVC
> PN pacing at high output

Quadripolar (4-10-4 mm) in the hepatic vein
> record diaphragmatic compound motor action potential (CMAP)



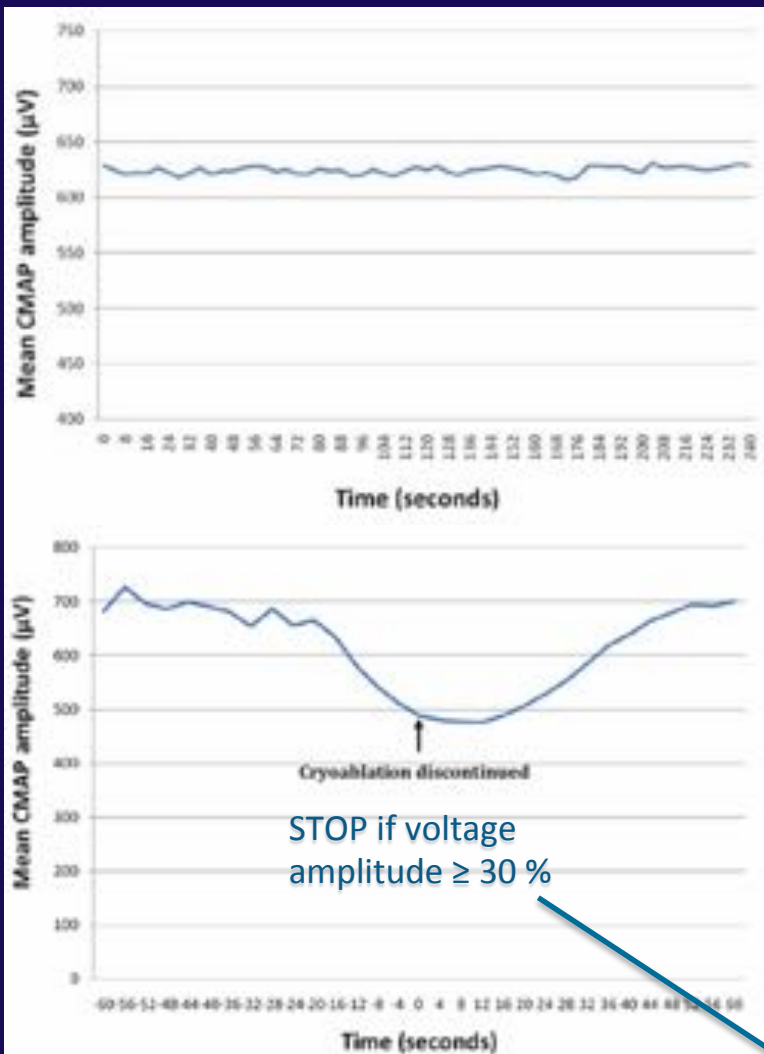
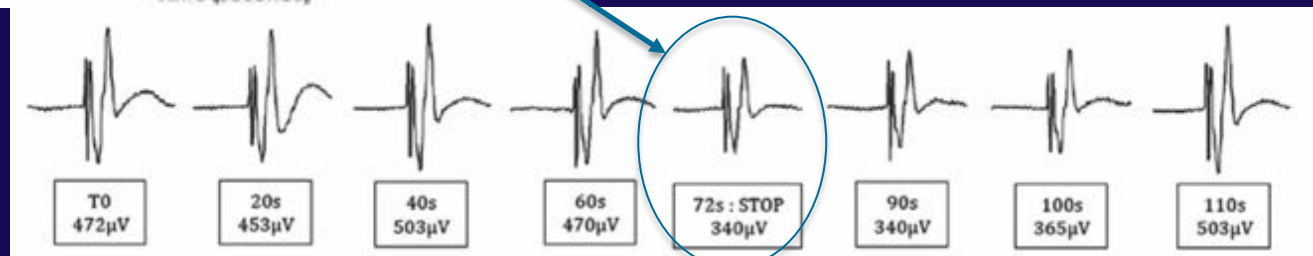


Table. Baseline Patient and Procedure Characteristics

| | |
|-----------------------------|------------|
| Patients included | 57 |
| Age, y | 59±9 |
| Male sex, n | 47 |
| Hypertension/ICM/DCM, % | 19.3/3.5/7 |
| LA diameter, mm | 39.9±2.3 |
| Paroxysmal/persistent, % | 86/14 |
| Procedural time, min | 144±29 |
| Fluoroscopy time, min | 30±12 |
| Cryoballoon applications, n | 9±2 |
| Cryoballoon 23/28/23–28 mm | 63/32/5 |

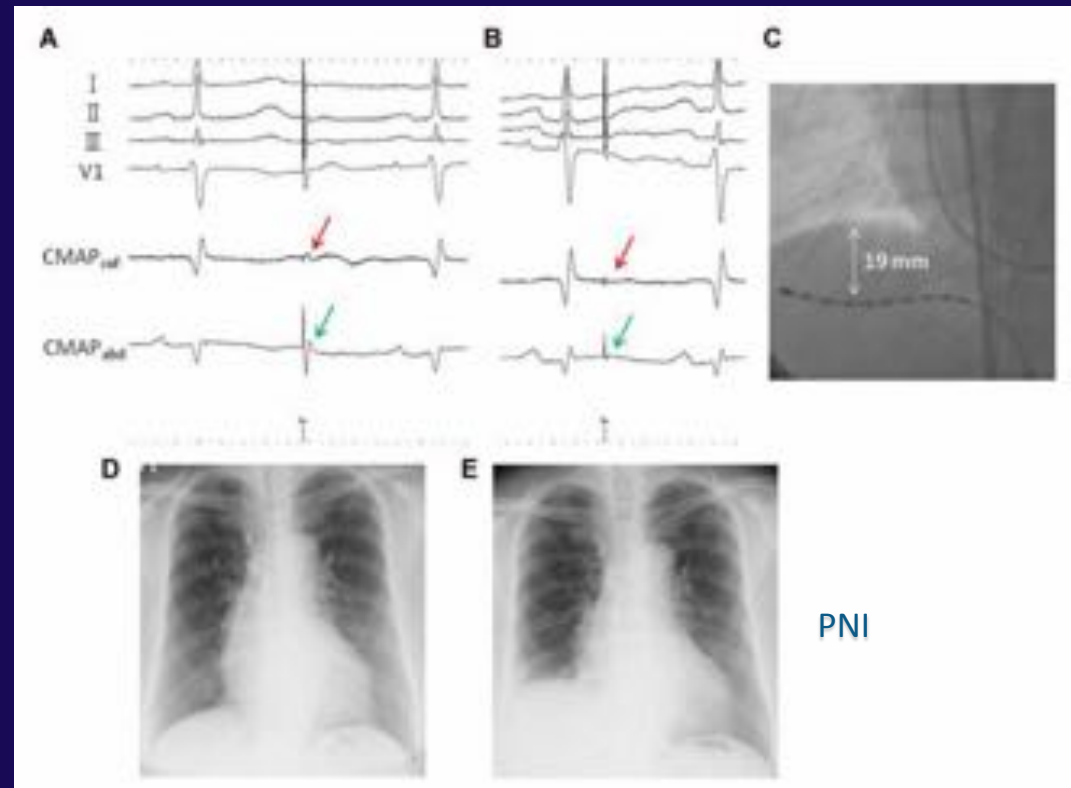
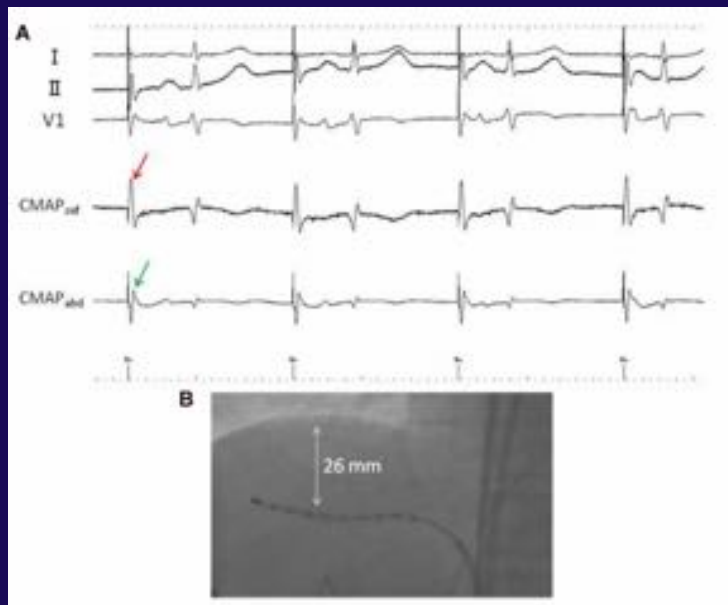
57 balloon-ablation procedures

- 50 stable PN capture
- 6 patients with CMAP amplitude reduction $\geq 30\%$
- No PN injury



Evaluation of Diaphragmatic Electromyograms in Radiofrequency Ablation of Atrial Fibrillation: Prospective Study Comparing Different Monitoring Techniques

SHINSUKE MIYAZAKI, M.D.,* NOBORU ICHIHARA, M.D.,* HIROSHI TANIGUCHI, M.D.,*
HITOSHI HACHIYA, M.D.,* HIROAKI NAKAMURA, M.D.,* EISUKE USUI, M.D.,*
YOSHIHISA KANAJI, M.D.,* TAKAMITSU TAKAGI, M.D.,* JIN IWASAWA, M.D.,*
AKIO KUROI, M.D.,* KENZO HIRAO, M.D.,† and YOSHITO IESAKA, M.D.*



Conclusions

- Uninterrupted coumadin and factor X during ablation of atrial fibrillation and left atrial flutter appear to reduce the risk of thromboembolic complications without increasing the risk of bleeding
- This approach benefits more non paroxysmal AF patients which carry a higher risk of such complication

Conclusions

- Therefore, the protective effects of new drugs should be tested in non paroxysmal patients

Be Careful...

Know what you are doing...

Keep Your Eyes on the Target

