

# Current, Competing and Emerging Technologies in the Ablation of Atrial Fibrillation

Vivek Y. Reddy, MD

## Current, Competing and Emerging Technologies in the Ablation of Atrial Fibrillation

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The Mount Sinai Hospital



## Disclosures

- Grant support and/or Consultant:
  - Biosense-Webster Inc, Cardiofocus Inc, Endosense Inc, Hansen Medical Inc, Magnetecs Inc, Medtronic-Cryocath Inc, Philips Inc, St Jude Medical Inc, Voyage Medical Inc
- I will be discussing off-label use of catheter ablation devices.

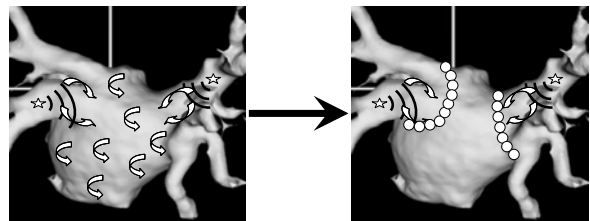


## Outline

- What is the success rate of PV isolation?
- Ablation of Paroxysmal AF
  - Imaging
  - Improving point-to-point ablation
  - One-size-fits-all devices
- Ablation of Persistent AF



## Paroxysmal AF: Catheter Ablation

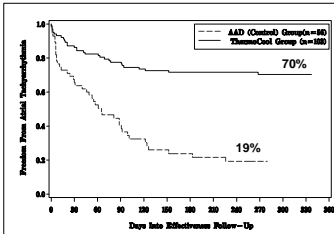


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## Ablation vs Medications for PAF

### ASIA Randomized Atrial Fibrillation



Wilber et al, JAMA, 2010

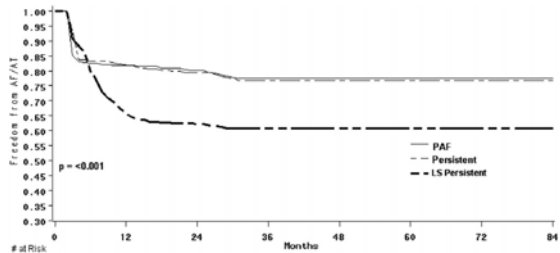
### Safety

- Ablation Group (6.8%, n=103)
  - 1 pericarditis
  - 1 pulmonary edema
  - 1 pericardial effusion (no tx needed)
  - 5 vascular complications
  - No Stroke/Embolism, Tamponade, Atrio-Esophageal fistula, PV stenosis, or Phrenic nerve paralysis
- AAD group (17.9%, n=56)
  - 3 life-threatening ventricular arrhythmias
  - 7 disabling symptoms requiring drug withdrawal
- One death in Ablation group, at 204 days, due to acute MI.

## Ablation vs AADs: 1 yr Success

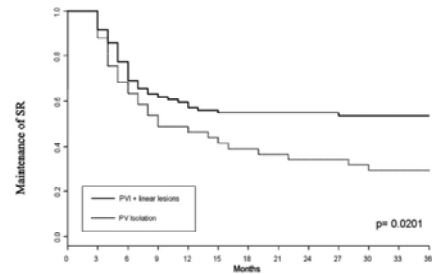
Study	AADs Success Rate	Ablation Success Rate	2 <sup>nd</sup> Ablations	Still on AADs
A4	23%	89%	80%	0%
Thermocool IDE	17%	63%	13%	7%
STOP-AF	7%	70%	19%	12%
CABANA Pilot	38%	61%	21%	28%

## Long-term Outcome after PVI: Single Procedure Outcome



Bhargava M et al. Heart Rhythm 2009; 6:1403-1412

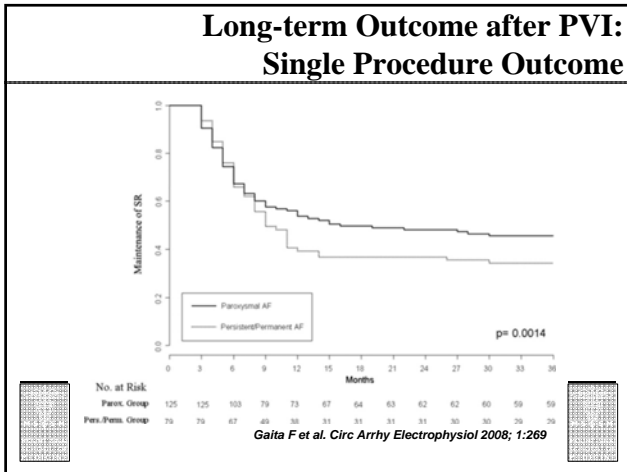
## Long-term Outcome after PVI: Single Procedure Outcome



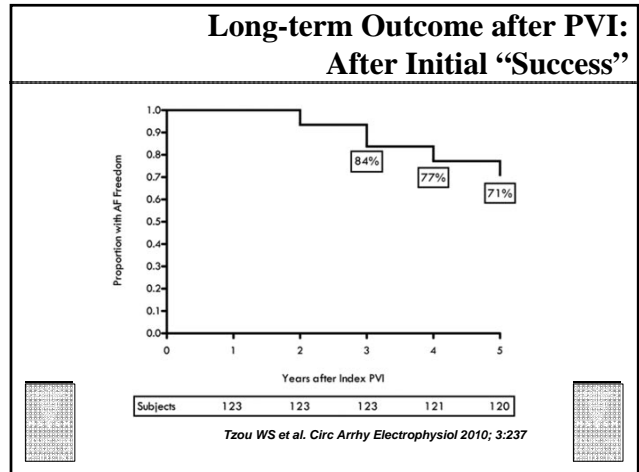
No. at Risk:  
 PVI Group: 41 41 31 24 22 19 17 16 15 15 14 13 13  
 PVI + linear lesions Group: 84 84 72 55 51 48 47 47 47 46 46 46 46

Gaita F et al. Circ Arrhy Electrophysiol 2008; 1:269

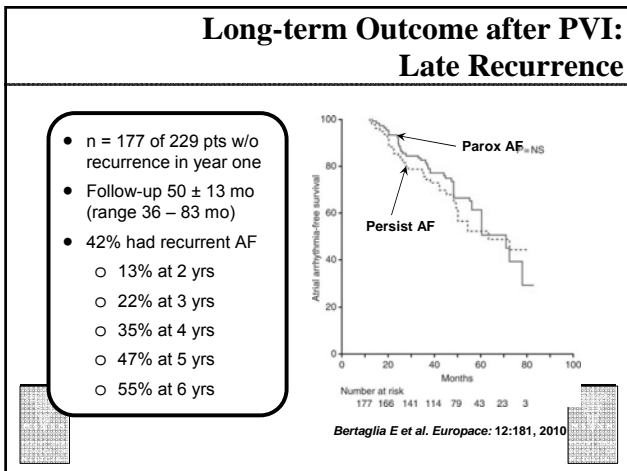
## Long-term Outcome after PVI: Single Procedure Outcome



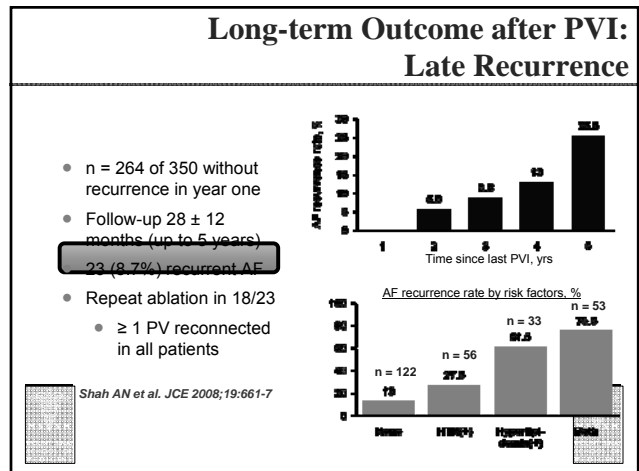
## Long-term Outcome after PVI: After Initial "Success"



## Long-term Outcome after PVI: Late Recurrence



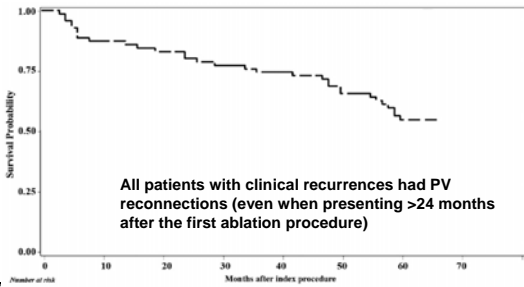
## Long-term Outcome after PVI: Late Recurrence



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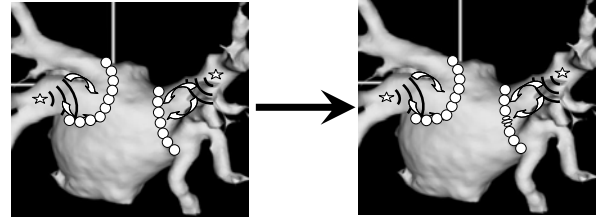
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## Long-term Outcome after PVI: Single Procedure Outcome

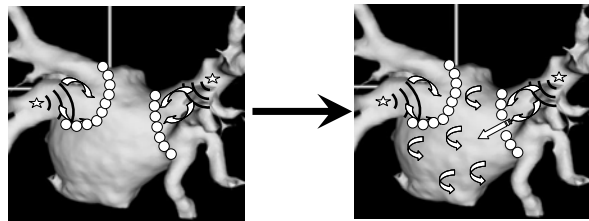


Sawhney *et al. Am J Cardiol* 2009; 104:366

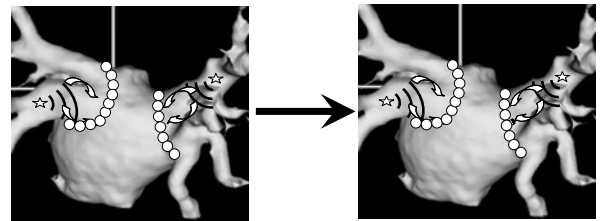
## Paroxysmal AF: Why does ablation fail?



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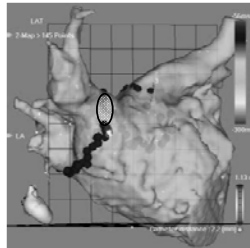


# Current, Competing and Emerging Technologies in the Ablation of Atrial Fibrillation

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## How often does PV reconnection occur?

- How frequent is PV reconnection?
- Pratola et al, *Circulation* 2008; 117:136
- PV encircling procedure for drug-refractory Atrial Fibrillation
- Repeat EPS in 20 pts
  - Persistent PV isolation: 37.5%
  - Persistent PV exit block: 48.7%



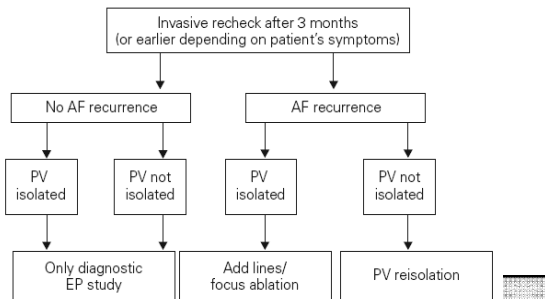
## How often does PV reconnection occur?

- S.Willems et al, *JCE* 2010 (in press)
- Methodology:
  - 64 pts with PAF underwent PVI (Robotic Nav-Hansen + NavX)
  - Repeat pre-specified EPS performed in 40 pts at 3 months
- Persistent PV Isolation:
  - On a per vein basis: 57%
  - On a per patient basis: 23% (ie, pts with all PVs isolated)

Pattern of PV Reconnection during Follow-Up EPS in Patients with and without AF Recurrence

Reconnected PV	Free of AF Recurrence (n = 28)	AF Recurrence (n = 12)	P-Value
0 (%), (n)	32 (9)	0 (0)	
1 (%), (n)	21 (6)	0 (0)	
2 (%), (n)	29 (8)	58 (7)	
3 (%), (n)	11 (3)	33 (4)	
4 (%), (n)	7 (2)	8 (1)	
Mean	1.4	2.5	0.006

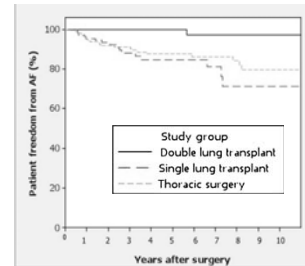
## How often does PV reconnection occur? The GAP-AF Trial



Breithardt G et al. *Herz* 33:548-555, 2008

## What if durable PV Isolation?

- Lee G et al, *Eur Heart J*, 2010
- AF after lung transplantation
  - Compare early & late AF
  - Retrospective analysis after:
    - Single Lung Transplantation
    - Double Lung Transplantation
    - Thoracic Surgery



Number of patients at risk:

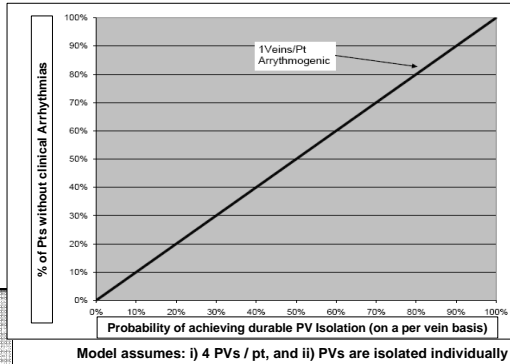
DLT	200	174	157	146	141	139	135	133	132	132	132
SLT	127	103	83	63	49	46	39	37	33	33	33
THR	201	167	155	153	147	146	145	145	143	140	140

- Early post-op AF:
  - Double Lung 29%
  - Single Lung 28%
  - Thoracic Surg 14%

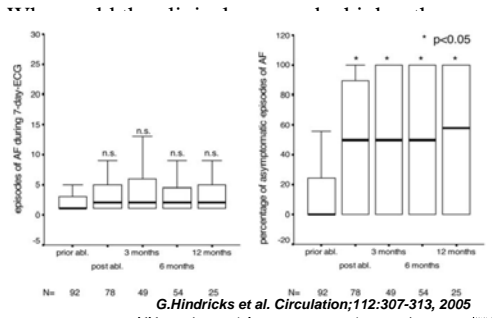
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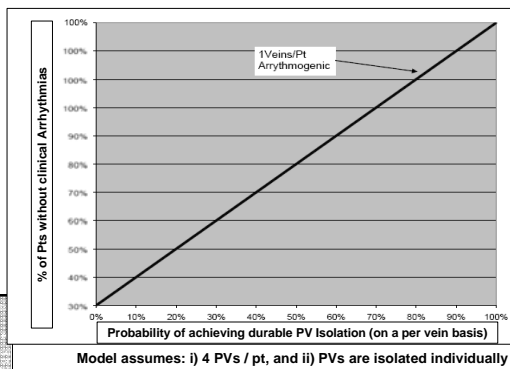
## Importance of Durable PV Isolation



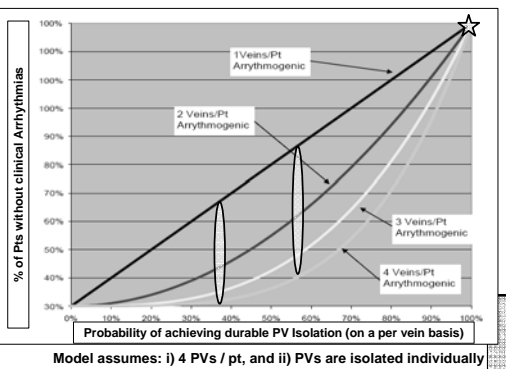
## Why would there be a discordance between Durable PV Isolation and Clinical AF?



## Correlation of PVI & Clinical Success



## Correlation of PVI & Clinical Success

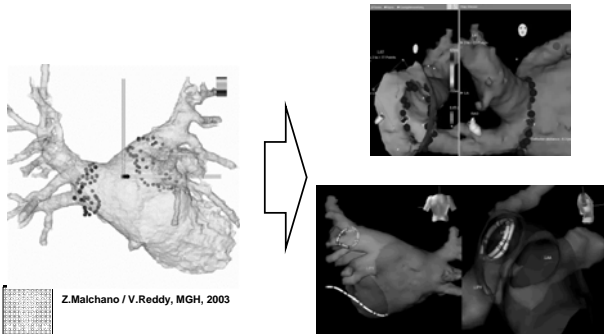


## How can we improve lesion formation?

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1. Image-Guidance
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- One-size-fits-all devices
6. Cryo-Balloon
7. Visually-guided Laser Balloon
8. Curvilinear Catheters

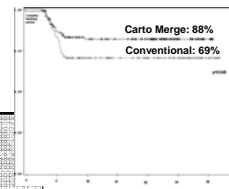
## CT/MR Image-Guided Therapy



## Image-Guided Therapy: Clinical Data

	Procedural Characteristics		P
	Group 1*	Group 2†	
Fluoroscopy time (minutes)	56 ± 18	45 ± 12	<0.0001
Procedural duration (minutes)	170 ± 20	150 ± 23	<0.0001
Mean total energy delivered (J)	76,550 ± 12,400	67,270 ± 11,800	<0.0001
Mean RF delivery times (min)	49 ± 13	46 ± 14	= 0.08
Mean radiation exposure (mGy*min)	28,775 ± 3,540	21,340 ± 2,335	<0.001
Effective biological dose (mSv)	78 ± 14 (first 40 cases)	44 ± 5	<0.001
	65 ± 11 (last cases)		

\*Radiation times of the ablation procedure and the CT scan acquisition.  
 †Radiation times of the ablation procedure including the venography.



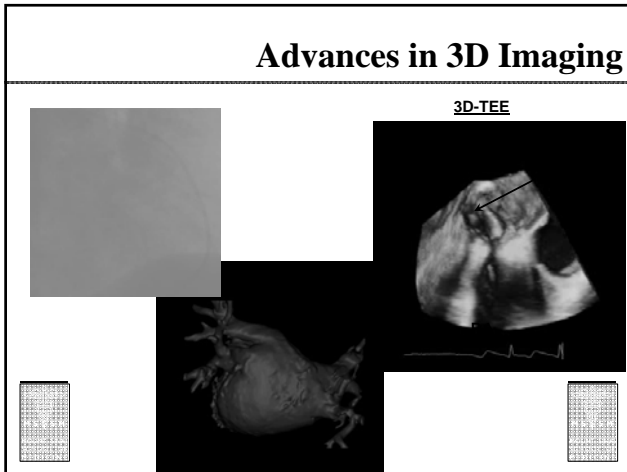
**290 pts Randomized to:**  
**Image-Guided (145, parox:73%)**  
 or  
**Conventional (145, parox: 69%)**

Della Bella et al, JCE 20:258 (2009)

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## Advances in 3D Imaging



## Radiation: Estimated Cancer Risk

	Effective Dose (mSv)	Lifetime Attributable Risk (%)	
		All Cancer Incidence	All Cancer Mortality
BMI <25 kg/m <sup>2</sup>	15.2 ± 7.9	0.100 ± 0.060 (1/1,000)	0.060 ± 0.033 (1/1,666)
BMI 25-30 kg/m <sup>2</sup>	26.8 ± 11.6	0.158 ± 0.080 (1/633)	0.100 ± 0.048 (1/1,000)
BMI ≥30 kg/m <sup>2</sup>	39.0 ± 14.7	0.247 ± 0.083 (1/405)	0.149 ± 0.049 (1/671)
All patients	25.0 ± 13.8	0.156 ± 0.090 (1/641)	0.095 ± 0.053 (1/1,053)

Ector et al, JACC 50:234, 2007

## Radiation Exposure to Staff

**Table 1**

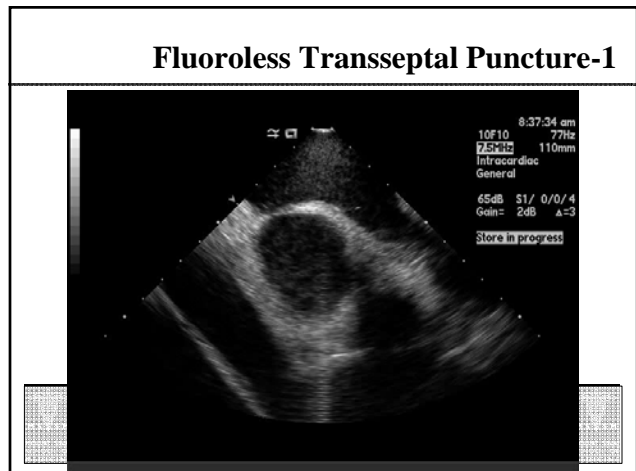
Orthopedic Complications		
Author (reference #)	Methods	Findings
Ross (1)	Survey of interventional cardiologists (852 surveys, 385 responses), orthopedists (577 surveys, 131 responses) and rheumatologists (878 surveys, 198 responses)	Increased spine problems in interventionalists (75% incidence) as compared to orthopedists and rheumatologists
Goldstein (2)	Survey of 1600 interventional cardiologists (424 responses)	Prevalence of orthopedic complaints: Spine 42% Hip, knee, ankle 28% Spine problem limited work in 1/3
Mechan (12)	Survey of interventional radiologists (308 responses)	60% reported spine complaints; in 25%, spine problems limited work
Moore (13)	Survey of 608 radiologists (236 responses)	50% prevalence of back pain

**Table 2**

Cancer Incidence		
Author (reference #)	Methods	Findings
Finkelstein (18)	Report of a case cluster	Brain cancer in 2 interventionalists
Preston (21)	Review of solid cancers in atomic bomb survivors	Radiation dose response for nervous system tumors.
Matanoski (23)	Cohort study of mortality in radiologists over a 50 y period	Exposure to dose <-1 Sv associated with increased risk for leukemia and lymphoma
Carozza (25)	Case control study of occupation and glioma	Physicians at increased risk of glioma
Andersen (26)	Population based study of occupation and cancer incidence	Brain cancer increased among physicians in general. No breakdown by specialty.

Klein et al, Radiology 250:538, 2009

## Fluorless Transseptal Puncture-1

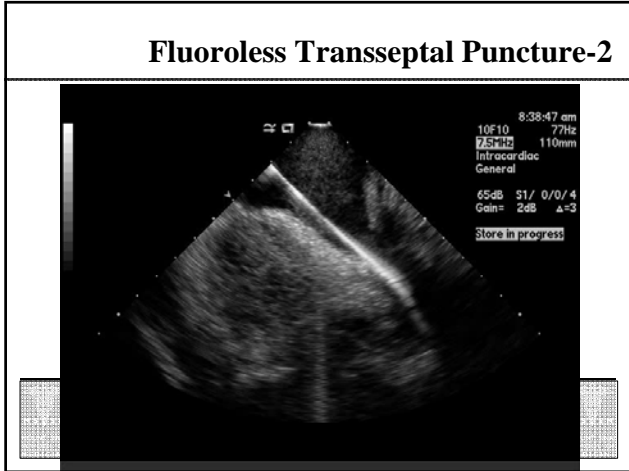




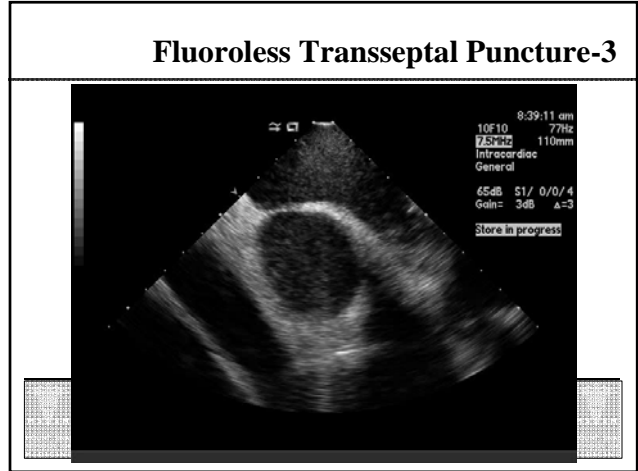
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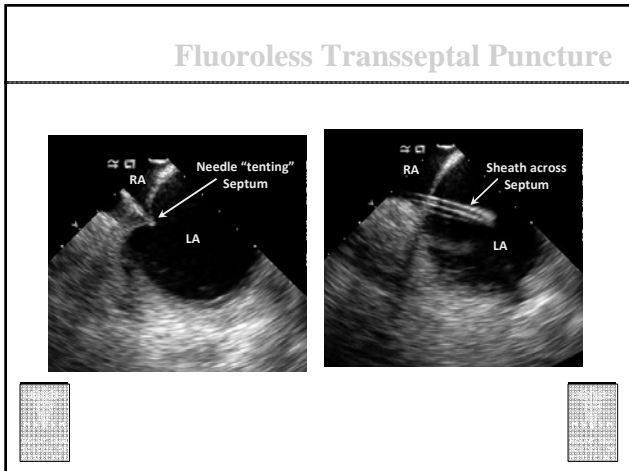
### Fluoroless Transseptal Puncture-2



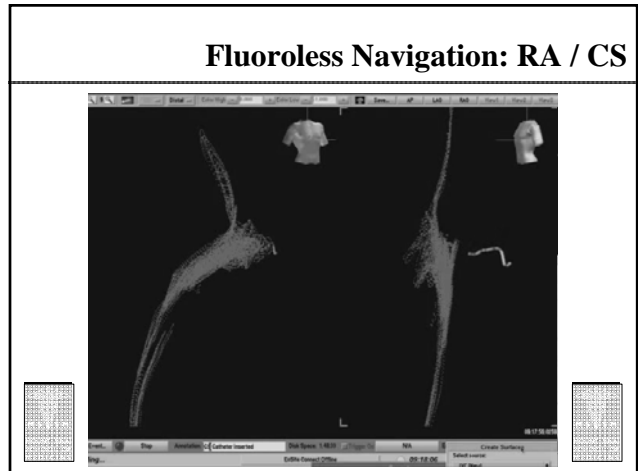
### Fluoroless Transseptal Puncture-3



### Fluoroless Transseptal Puncture



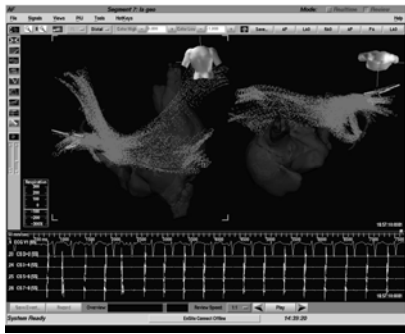
### Fluoroless Navigation: RA / CS



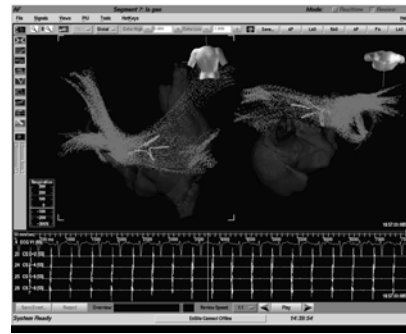
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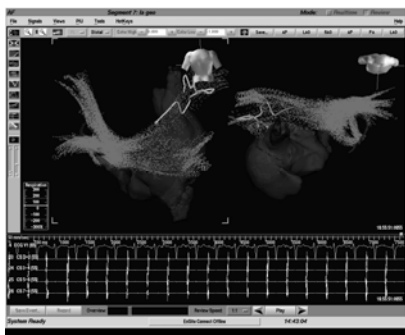
### LA Geometry: Multi-spline Catheter



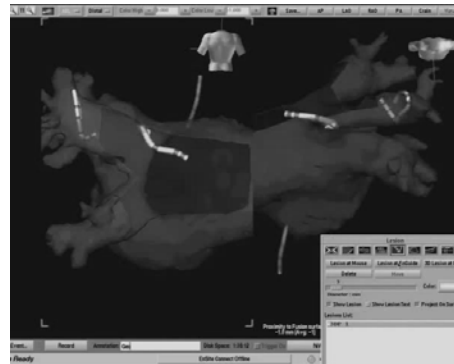
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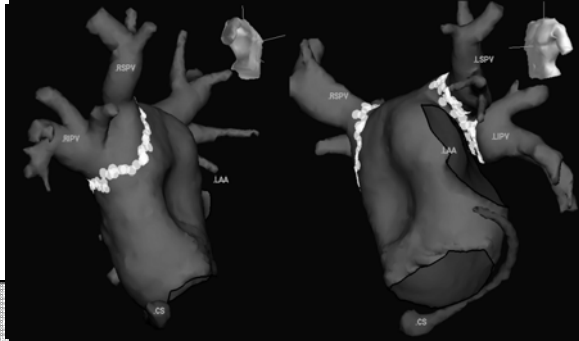
### Where is the transseptal sheath?



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## Fluoro-less AF Ablation



## Procedural Details

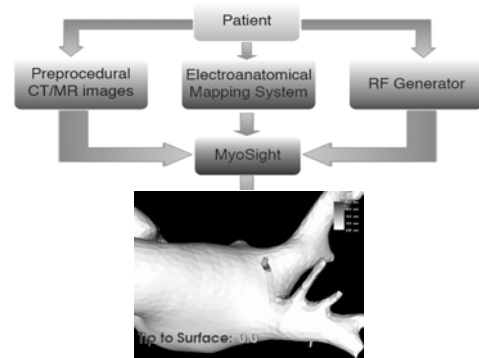
Parameter	Value
No. of TS punctures	1 (18 pts), 2 (2 pts)
Catheter used, Circular/Flower	70% / 30%
Time for RA geometry, min	5.5 ± 2.6 (2 – 11)
Time for LA geometry, min	22 ± 10 (8 – 40)
CT Registration used, n	11 pts (55%)
Time for CT Registration, min	19 ± 8 (9 – 34)
No. of RF Lesions	49 ± 18 (15 – 101)
Total Time of RF Delivery, min	53 ± 18 (18 – 104)
Success of Isolating Lesion Sets	38/39 (97%)
Time from first to last lesion, min	113 ± 44 (42 – 217)
Total Procedure Time, min	244 ± 75 (125 – 454)

V.Reddy et al *Heart Rhythm* (accepted)

## How can we improve lesion formation?

1. Image-Guidance
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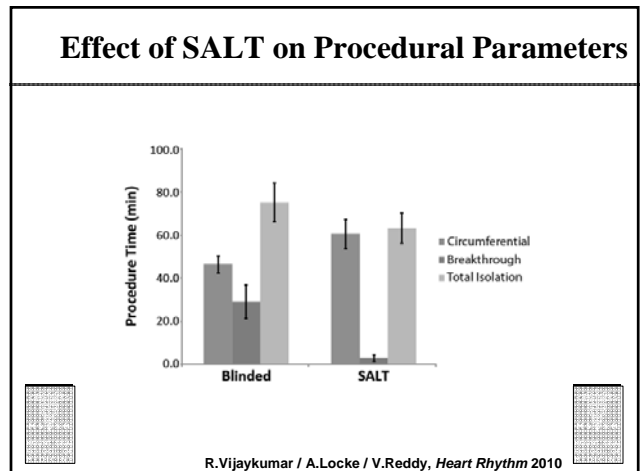
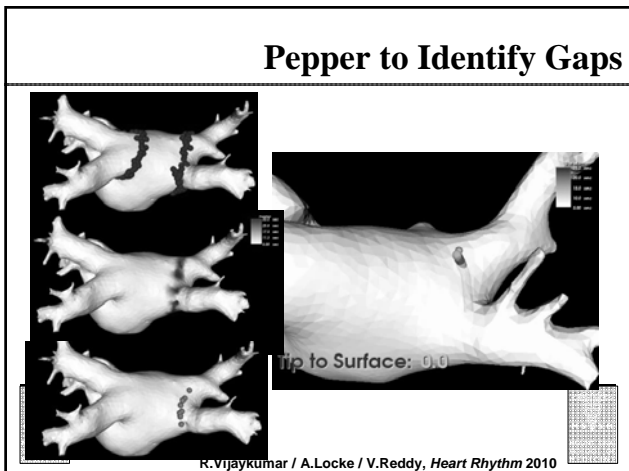
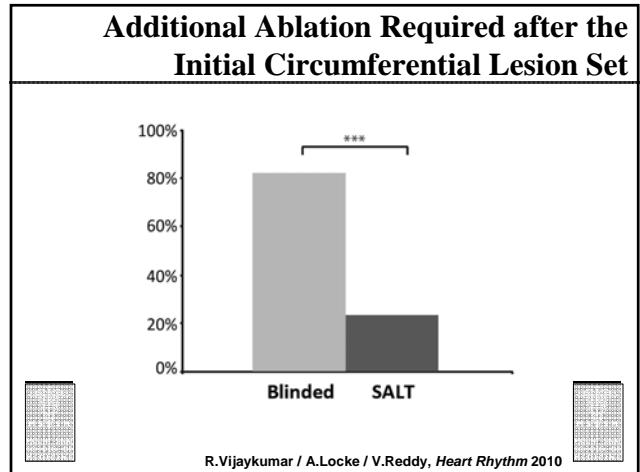
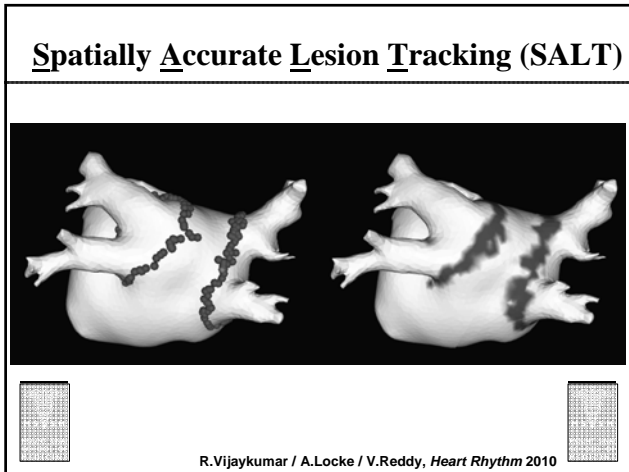
## Can we improve lesion tracking?



R.Vijaykumar / A.Locke / V.Reddy, *Heart Rhythm* 2010

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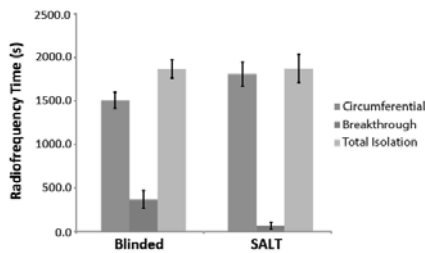
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## Effect of SALT on Procedural Parameters



R.Vijaykumar / A.Locke / V.Reddy, *Heart Rhythm* 2010

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## Can Pace-Capture Facilitate Ablation?

### Anatomical Encircling

- Irrigated RF Catheter
- PV potentials hidden
- Ipsilateral PVs as pairs

### Render Non-Capturable

- Pace-Capture on lines
- More RF till non-capture

### Un-blind Operator

- Assess whether isolation
- More RF if not isolated

- 30 PAF patients (2 centers)
- After anatomical encircling, PVI occurred in 19/60 (32%)
- After PC, PVI in 57/60 (95%)
- More RF: PVI in 60/60(100%)
- Even after PVI, additional sites of pace-capture in 30/60 (50%)

D.Steven / V.Reddy / G.Michaud, *Heart Rhythm*, 2009 (in press)

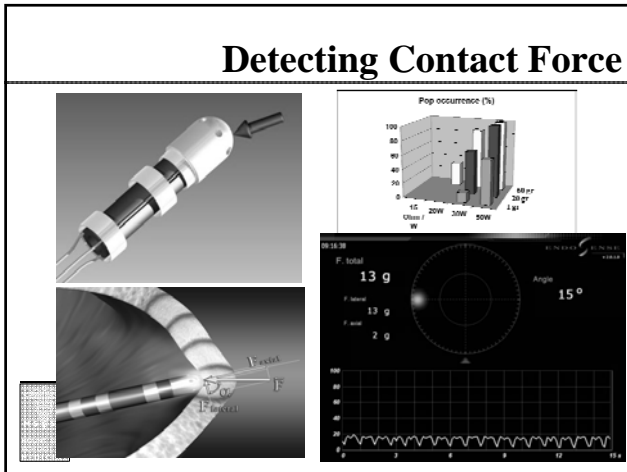
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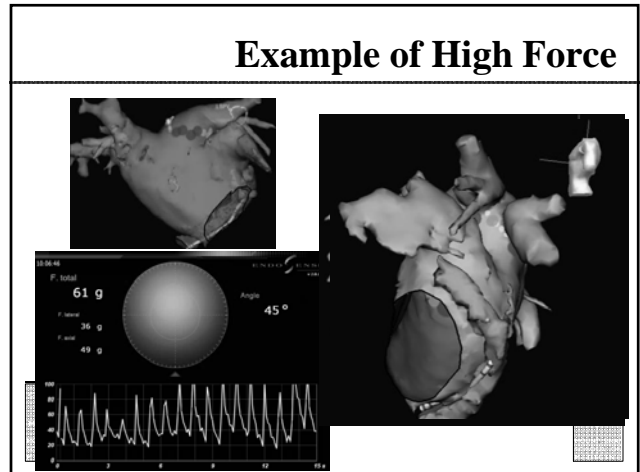
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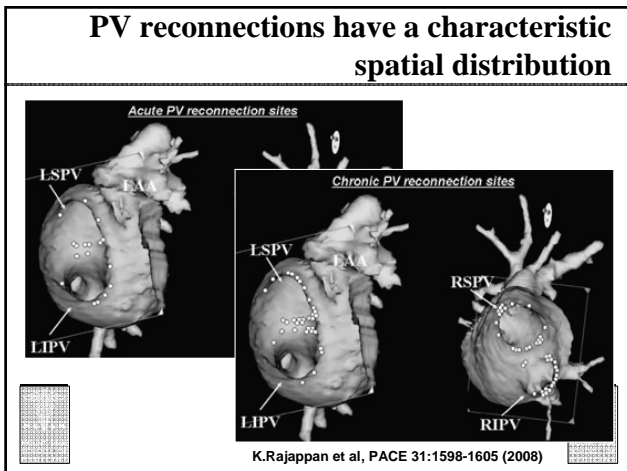
## Detecting Contact Force



## Example of High Force

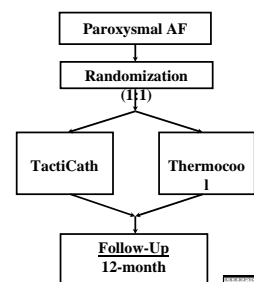


## PV reconnections have a characteristic spatial distribution



## TOCCASTAR

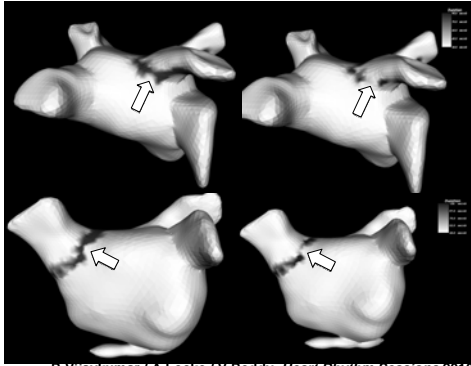
- Randomized FDA-IDE Trial
  - Centers: US & Europe
  - PI: Vivek Reddy
  - Compare TactiCath to Thermocool ablation catheter for AF ablation
- Non-inferiority Study
- Endpoints:
  - 1<sup>o</sup> Efficacy:
    - 12-mo AF/AT free rate off AADs
  - 1<sup>o</sup> Safety: Procedure-related events
  - Secondary Endpoints:
    - Number of gaps after encircling lesions
    - Total duration of RF Energy required
    - Time to achieve PV Isolation



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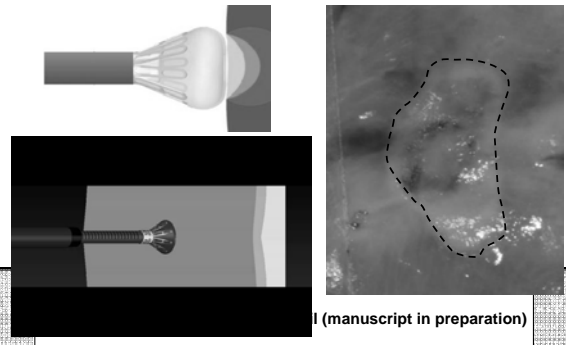
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## Pepper vs Force-Pepper



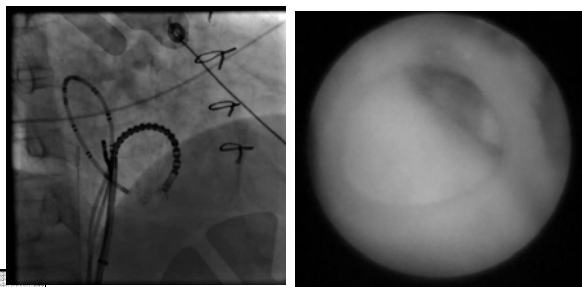
R.Vijaykumar / A.Locke / V.Reddy, *Heart Rhythm Sessions 2010*

## In Vivo Visually-Guided Spot Ablation



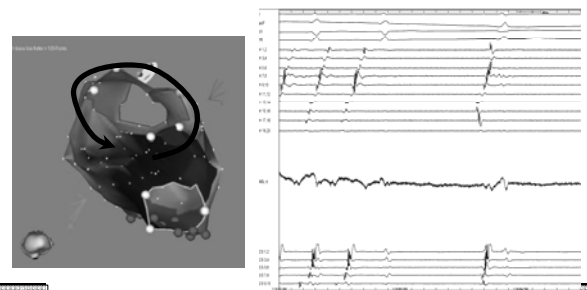
(manuscript in preparation)

## In Vivo Visually-Guided A.Flutter Ablation



V.Reddy / P.Neužil (manuscript in preparation)

## In Vivo Visually-Guided A.Flutter Ablation

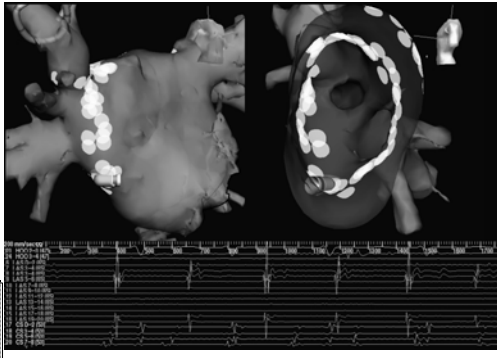


V.Reddy / P.Neužil (manuscript in preparation)

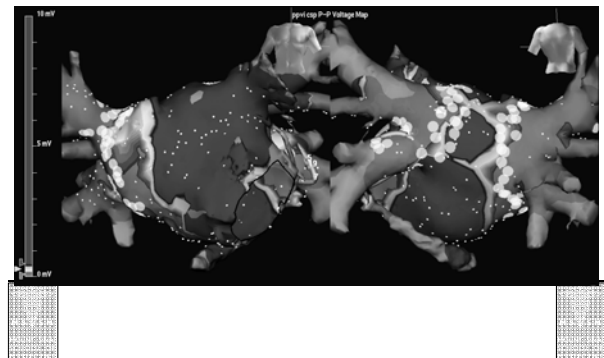
# Current, Competing and Emerging Technologies in the Ablation of Atrial Fibrillation

Vivek Y. Reddy, MD

## In Vivo Visually-Guided AF Ablation



## In Vivo Visually-Guided AF Ablation



## How can we improve lesion formation?

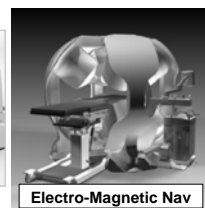
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## Remote Navigation Systems

- Magnetic Navigation: Fixed Magnets (Stereotaxis)
- Magnetic Navigation: Electro-Magnets (Magnetecs)
- Robotic Navigation (Hansen Medical)



Fixed Magnetic Nav



Electro-Magnetic Nav



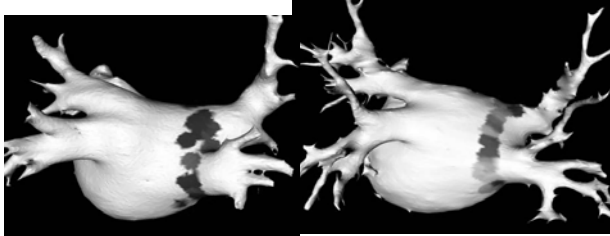
Robotic Nav



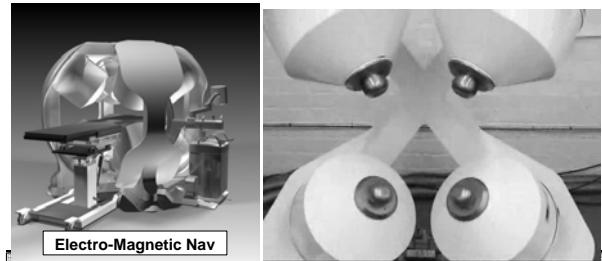
# Current, Competing and Emerging Technologies in the Ablation of Atrial Fibrillation

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## Stability of Remote vs Manual Ablation



## Electro-Magnetic Navigation



## Electro-Magnetic Navigation



## Electro-Magnetic Navigation



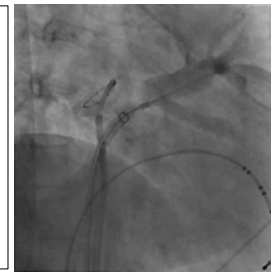
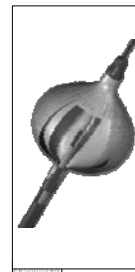
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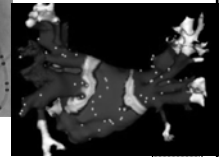
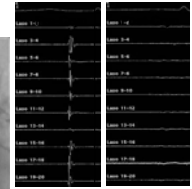
## How can we improve lesion formation?

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## Cryoballoon Ablation



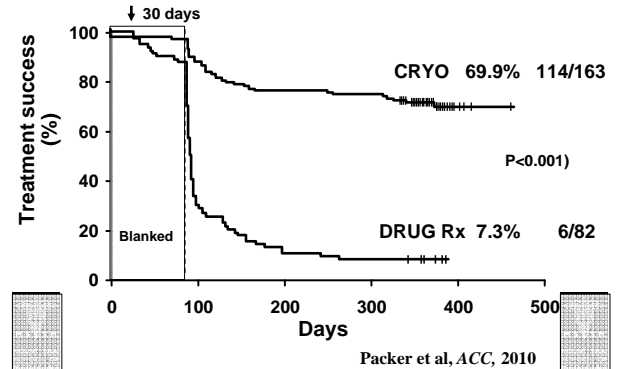
LSPV



## Clinical Outcome

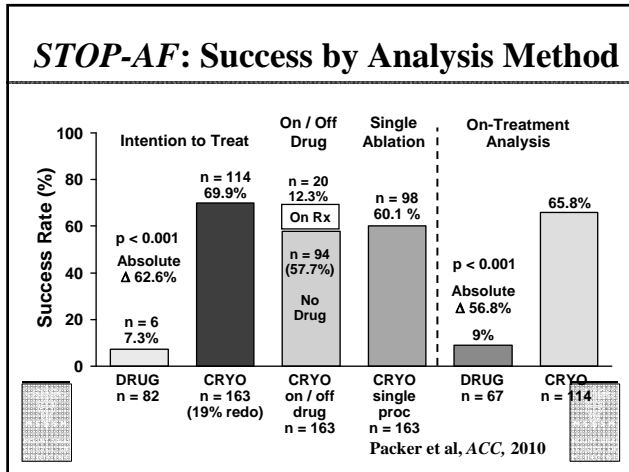
Study	N	Follow-Up	Freedom from AF	
			Paroxysmal	Persistent
Reddy et al, AHA 2005	20	12 mo	84%	---
Klein et al, <i>Heart Rhythm</i> 2008	21	6 mo	86%	---
Neumann et al, <i>JACC</i> 2008	293 / 53	12 mo	74%	42%
Linhart et al, HRS 2008	20	3 mo	50%	---
VanBelle et al, <i>Cardiostim</i> 2008	100	12 mo	64%	---
Knob et al, GCS 2008	28 / 12	8.8 mo	43%	42%
Packer et al, STOP-AF	163	12 mo	69.9%	---

## STOP-AF US IDE Trial



# Current, Competing and Emerging Technologies in the Ablation of Atrial Fibrillation

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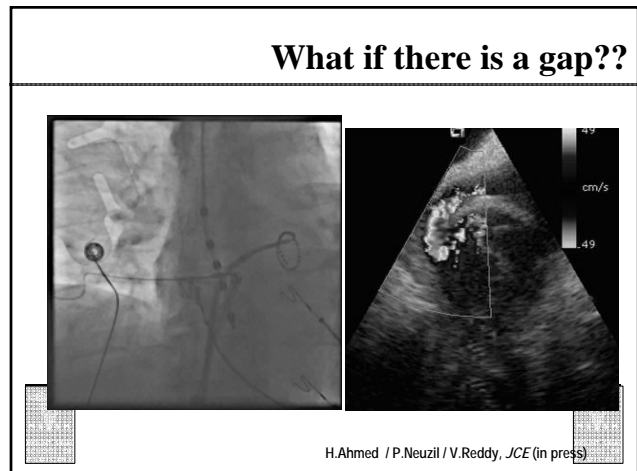


### STOP-AF: Adverse Events

Type of Adverse Event	CRYO (n = 163)	DRUG (n = 82)
Stroke	4 (2.5%)	1 (1.2%)
TIA	3 (1.8%)	1 (1.2%)
Tamponade	1 (0.6%)	1 (1.2%)
Myocardial infarction	2 (1.2%)	0 (0.0%)
Hemorrhage requiring transfusion	3 (1.8%)	1 (1.2%)
New atrial flutter	6 (3.7%)	13 (15.9%)
Atrial esophageal fistula	0 (0.0%)	0 (0.0%)
Death	1 (0.6%)	0 (0.0%)
New or worsened AV fistula	2 (1.2%)	0 (0.0%)
Pseudoaneurysm	1 (0.6%)	1 (1.2%)
Phrenic nerve palsy	22 (13.5%)	6 (7.3%)
Persistent phrenic nerve palsy	4 (2.5%)	0 (0.0%)
PV stenosis	5 (3.1%)	2 (2.4%)

Source: Packer et al, ACC, 2010.

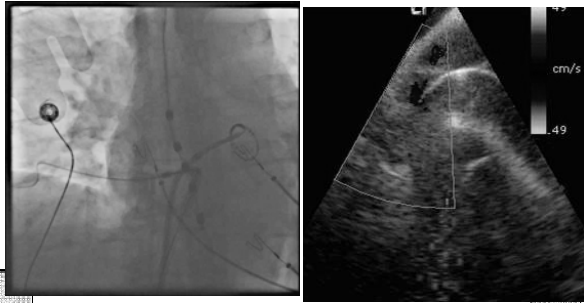
- ### STOP-AF: Problems with the Cryoballoon
- Efficacy: Chronic PVI
  - Safety Considerations
    - Tamponade
    - Stroke
    - Phrenic Nerve Paralysis
    - Pulmonary Vein Stenosis



# Current, Competing and Emerging Technologies in the Ablation of Atrial Fibrillation

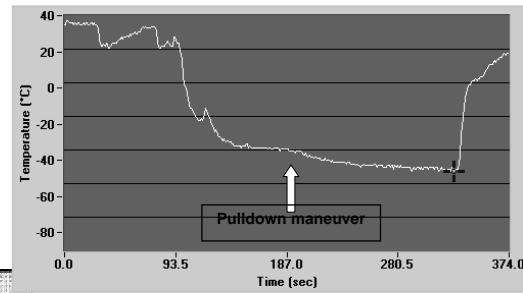
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## What if there is a gap??



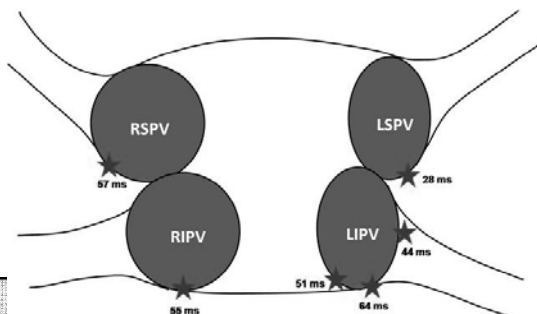
H.Ahmed / P.Neužil / V.Reddy, *JCE* (in press)

## Pulldown: Effect on Balloon Temp



H.Ahmed / P.Neužil / V.Reddy, *JCE* (in press)

## Where are the chronic breakthroughs?



H.Ahmed / P.Neužil / V.Reddy, *JCE* (in press)

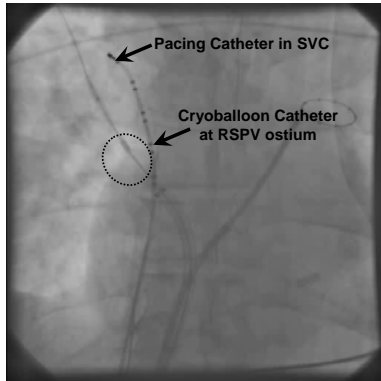
## STOP-AF: Problems with the Cryoballoon

- Efficacy: Chronic PVI
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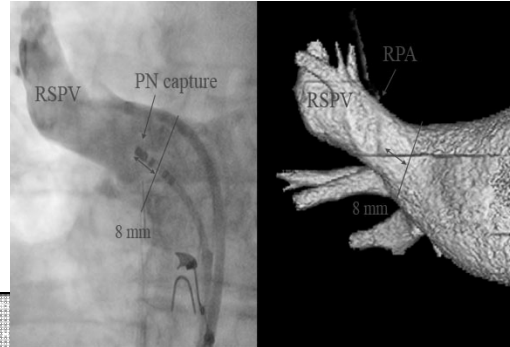
# Current, Competing and Emerging Technologies in the Ablation of Atrial Fibrillation

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## Minimizing Phrenic Nerve Injury

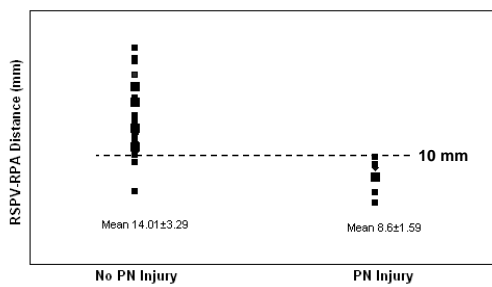


## Imaging the Phrenic Nerve?



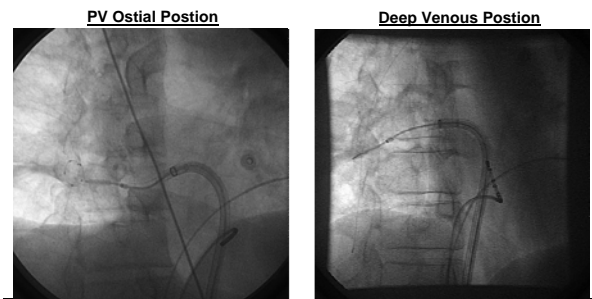
R.Horton / V.Reddy / A.Natale, *Heart Rhythm (in press)*

## Which patients with PN Injury?



R.Horton / V.Reddy / A.Natale, *Heart Rhythm (in press)*

## Why PV Stenosis after cryoballoon ablation?



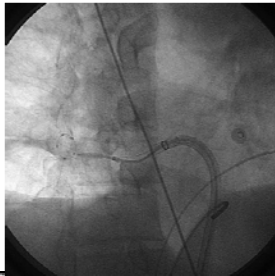
Courtesy of B.Schumacher

# Current, Competing and Emerging Technologies in the Ablation of Atrial Fibrillation

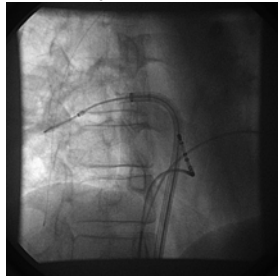
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## Why PV Stenosis after cryoballoon ablation?

PV Ostial Position



Deep Venous Position

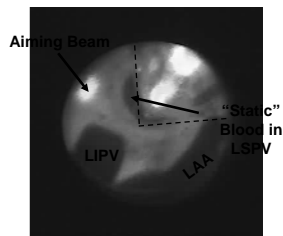
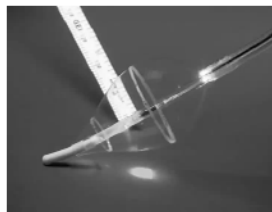


Courtesy of B.Schumacher

## How can we improve lesion formation?

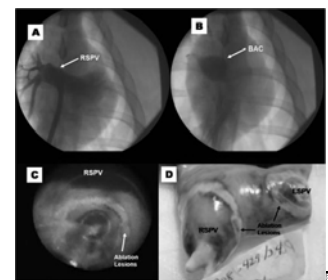
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## Visually-Guided Ablation



## Pre-Clinical Evaluation

- 17 Normal Pigs
  - 22 PVs targeted
  - 17 RSPVs, 5 LSPVs
- PV Isolation at 1<sup>st</sup> map
  - 21/22 (95%) PVs isolated
  - No PV stenosis/thrombus

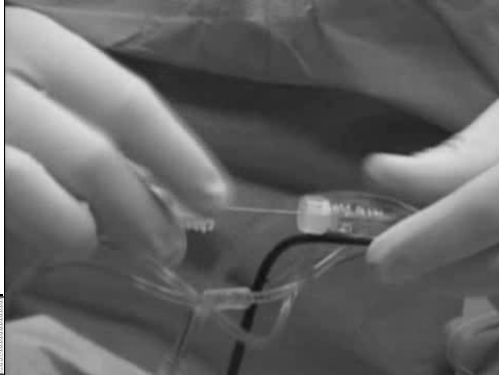


S.Dukkipati / P.Neuzil / A.d'Avila / V.Reddy, *Circ Arrhy* (in press)

# Current, Competing and Emerging Technologies in the Ablation of Atrial Fibrillation

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## *In vivo* Visually-Guided Ablation



## Pretreatment PV Sizes

	Mean $\pm$ SD	Min, Max
<b>LSPV (mm)</b>	19.9 $\pm$ 3.2	(15, 27)
<b>LIPV (mm)</b>	19.8 $\pm$ 3.3	(15, 30)
<b>RSPV (mm)</b>	22.7 $\pm$ 3.3	(17, 30)
<b>RIPV (mm)</b>	20.8 $\pm$ 3.3	(13, 26)
<b>LCPV (mm)</b>	27.8 $\pm$ 5.8	(20, 35)
<b>RCPV (mm)</b>	27.5 $\pm$ 0.7	(27, 28)

## Procedural Details

	Mean $\pm$ SD	Min, Max
<b>Procedure Time (hh:mm)</b>	3:16 $\pm$ 0:38	(2:16, 4:32)
<b>Fluoroscopy Time (min)</b>	19 $\pm$ 10	(7, 64)
<b>Ablation time (hh:mm)</b>	1:40 $\pm$ 0:27	(0:46, 2:27)

## Safety

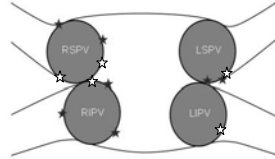
- No Device Related Adverse Events
  - 1 occurrence new onset atrial flutter
- No clot, char or steam pops
- No PV stenosis

# Current, Competing and Emerging Technologies in the Ablation of Atrial Fibrillation

Vivek Y. Reddy, MD

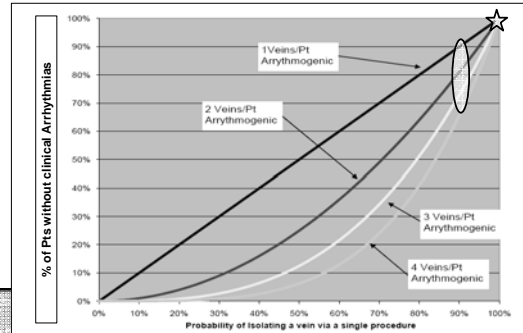
## Is Visually-Guided ablation permanent?

- Study in Prague:
  - Ablation in 40 pts
  - EP study at 10 weeks in all patients (regardless of sxs)
  - 33 pts came for 2<sup>nd</sup> procedure at  $11.1 \pm 0.9$  wks
- Results:
  - 33 patients  $\rightarrow$  127 PVs
  - Persistent Isolation
    - 113/125 PVs (90%)



S.Dukkkipati / P.Neuzil / A.d'Avila / V.Reddy, *Circ Arrhy* (in press)

## Correlation of PVI & Clinical Success



## How can we improve lesion formation?

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## Linear Ablation Technologies



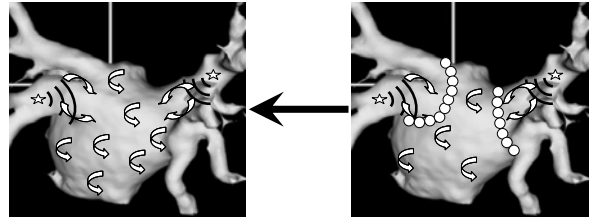


# Current, Competing and Emerging Technologies in the Ablation of Atrial Fibrillation

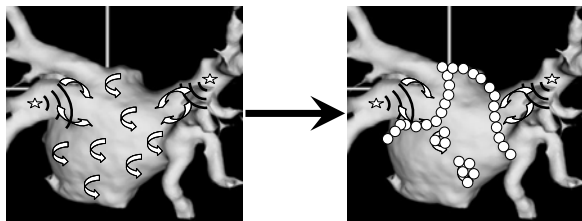
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What about Persistent AF?

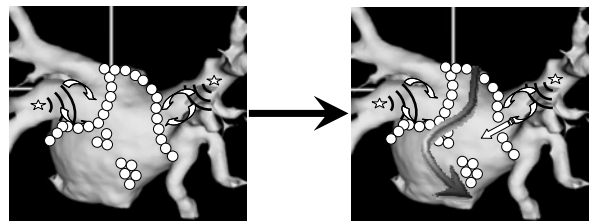
*Persistent AF: Catheter Ablation*



*Persistent AF: Catheter Ablation*

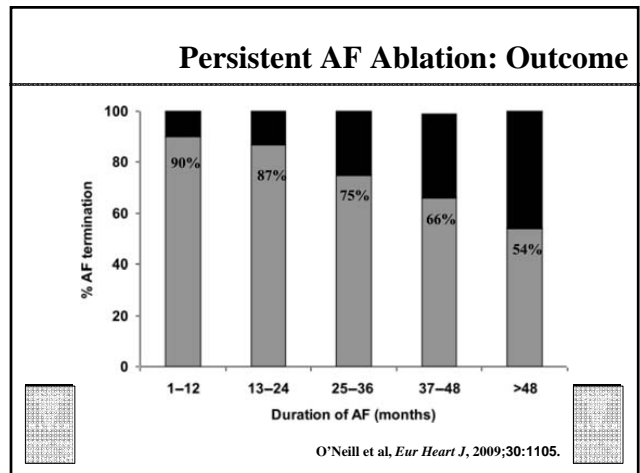
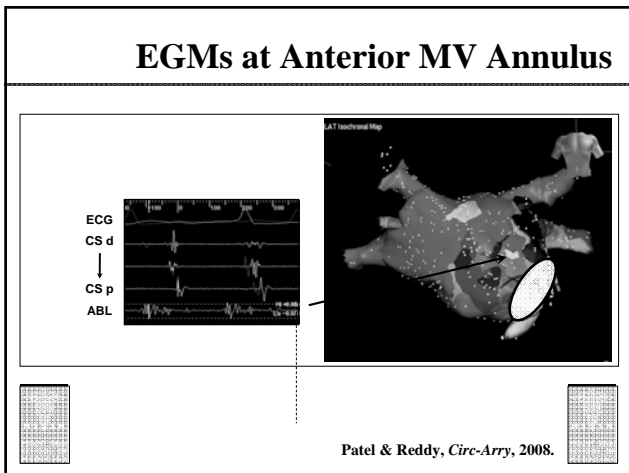
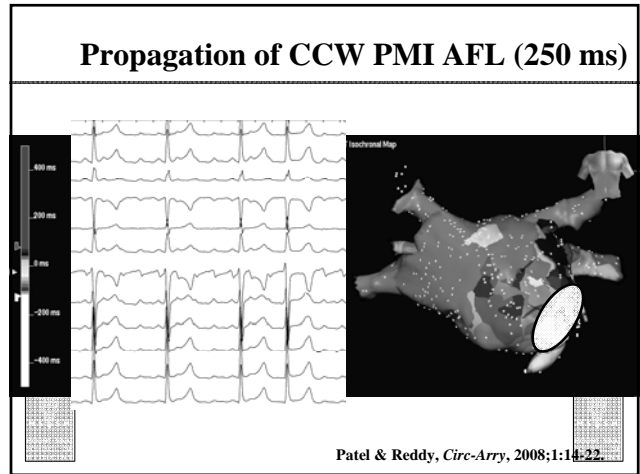
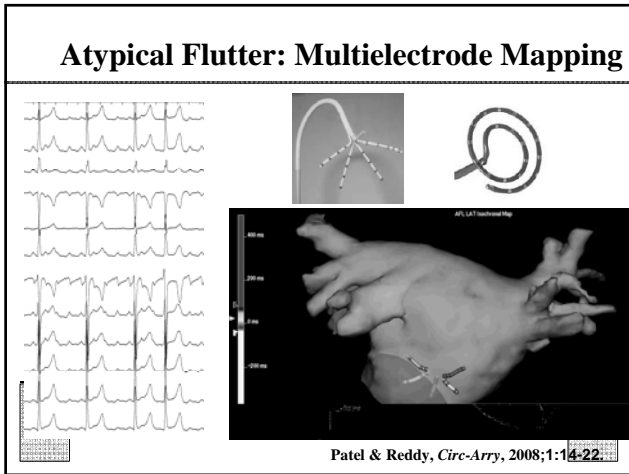


*Persistent AF: Why does ablation fail?*



# Current, Competing and Emerging Technologies in the Ablation of Atrial Fibrillation

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# Current, Competing and Emerging Technologies in the Ablation of Atrial Fibrillation

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## Final Thoughts

- Improving AF Ablation:
  - Need to achieve durable PV Isolation
  - PVI alone in persistent AF?
- Catheter Ablation of Paroxysmal AF
  - Goal is permanent PV Isolation
  - New technology is quite promising
    - Improving Point-by-Point Ablation
    - Remote Navigation
    - Balloon Ablation
- Persistent AF ablation
  - Ideally, ablate while still paroxysmal
  - Good outcome – but with multiple procedures

