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

Vivek Y. Reddy, MD

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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
### Ablation vs Medications for PAF

**Safety**
- Ablation Group (6.8%, n=103)
  - 1 pericarditis
  - 1 pulmonary edema
  - 1 pericardial effusion (no tx needed)
  - 5 vascular complications
  - No Sinus/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 284 days, due to acute MI.

### Ablation vs AADs: 1 yr Success

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

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


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Long-term Outcome after PVI: Single Procedure Outcome


- n = 177 of 229 pts w/o recurrence in year one
- Follow-up 50 ± 13 mo (range 36 – 83 mo)
- 42% had recurrent AF
  - 13% at 2 yrs
  - 22% at 3 yrs
  - 35% at 4 yrs
  - 47% at 5 yrs
  - 55% at 6 yrs

Long-term Outcome after PVI: After Initial “Success”


- n = 264 of 350 without recurrence in year one
- Follow-up 28 ± 12 months (up to 5 years)
- 23 (8.7%) recurrent AF
- Repeat ablation in 18/23
  - ≥ 1 PV reconnected in all patients

Long-term Outcome after PVI: Late Recurrence


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- Follow-up 50 ± 13 mo (range 36 – 83 mo)
- 42% had recurrent AF
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  - 47% at 5 yrs
  - 55% at 6 yrs

Long-term Outcome after PVI: Late Recurrence

Shah AN et al. JCE 2008;19:661-7

- n = 264 of 350 without recurrence in year one
- Follow-up 28 ± 12 months (up to 5 years)
- 23 (8.7%) recurrent AF
- Repeat ablation in 18/23
  - ≥ 1 PV reconnected in all patients

AF recurrence rate by risk factors:
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Long-term Outcome after PVI: Single Procedure Outcome

All patients with clinical recurrences had PV reconnections (even when presenting >24 months after the first ablation procedure)


Paroxysmal AF: Why does ablation fail?
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)

Preliminary data from the GAP-AF Trial


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

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

1. Image-Guidance
2. Lesion Indexing
3. Lesion Validation
   Improving point-to-point ablation
4. Contact Sensing Strategies
5. Remote Navigation
   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

<table>
<thead>
<tr>
<th>Clinical Characteristics</th>
<th>Group I*</th>
<th>Group II</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Procedural time (min)</td>
<td>25 ± 3</td>
<td>27 ± 3</td>
<td>&gt;0.05</td>
</tr>
<tr>
<td>Postprocedural LA volume</td>
<td>94 ± 25</td>
<td>82 ± 26</td>
<td>&gt;0.05</td>
</tr>
<tr>
<td>Procedural access route</td>
<td>Right</td>
<td>Right</td>
<td>&gt;0.05</td>
</tr>
<tr>
<td>Echocardiology of LA</td>
<td>29 ± 17</td>
<td>32 ± 19</td>
<td>&gt;0.05</td>
</tr>
<tr>
<td>LA Enlargement</td>
<td>&gt;150%</td>
<td>&gt;150%</td>
<td>&gt;0.05</td>
</tr>
</tbody>
</table>

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

Della Bella et al, JCE 20:258 (2009)
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Advances in 3D Imaging

3D-TEE

Radiation: Estimated Cancer Risk

<table>
<thead>
<tr>
<th>Effective Dose (mSv)</th>
<th>All Cancer Incidence</th>
<th>All Cancer Mortality</th>
</tr>
</thead>
<tbody>
<tr>
<td>BMI &lt;25 kg/m²</td>
<td>15.2 ± 7.0</td>
<td>0.100 ± 0.000</td>
</tr>
<tr>
<td>(1/1,000)</td>
<td>(1/1,000)</td>
<td>(1/1,000)</td>
</tr>
<tr>
<td>BMI 25-30 kg/m²</td>
<td>26.8 ± 11.6</td>
<td>0.158 ± 0.000</td>
</tr>
<tr>
<td>(1/1,033)</td>
<td>(1/1,000)</td>
<td>(1/1,000)</td>
</tr>
<tr>
<td>BMI ≥30 kg/m²</td>
<td>31.0 ± 14.7</td>
<td>0.247 ± 0.000</td>
</tr>
<tr>
<td>(1/469)</td>
<td>(1/476)</td>
<td>(1/476)</td>
</tr>
<tr>
<td>All patients</td>
<td>35.0 ± 13.8</td>
<td>0.186 ± 0.090</td>
</tr>
<tr>
<td>(1/641)</td>
<td>(1/503)</td>
<td>(1/503)</td>
</tr>
</tbody>
</table>

Ector et al, JACC 50:234, 2007

Radiation Exposure to Staff

Table 1

<table>
<thead>
<tr>
<th>Complication</th>
<th>Study Design</th>
<th>Method</th>
<th>Findings</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fluoroscopy exposure</td>
<td>Case-control</td>
<td>Radiological exams</td>
<td>Radiation dose exposure for various body regions</td>
</tr>
<tr>
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<td>Case-control</td>
<td>Radiological exams</td>
<td>Radiation dose exposure for various body regions</td>
</tr>
</tbody>
</table>

Table 2

<table>
<thead>
<tr>
<th>Cancer Incidence</th>
<th>Study Method</th>
<th>Findings</th>
</tr>
</thead>
<tbody>
<tr>
<td>Non-radiation</td>
<td>Case-control</td>
<td>Radiation dose exposure for various body regions</td>
</tr>
<tr>
<td>Radiation</td>
<td>Case-control</td>
<td>Radiation dose exposure for various body regions</td>
</tr>
</tbody>
</table>

Klein et al, Radiology 250:538, 2009

Fluoroless 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

Where is the transseptal sheath?
Fluoro-less AF Ablation

Procedural Details

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

How can we improve lesion formation?

1. Image-Guidance
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   Improving point-to-point ablation
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Can we improve lesion tracking?

- Preprocedural CT/MR images
- Electrocantopical Mapping System
- RF Generator
- Mynight
- Patient
- Surface 3D Mapping
- R.Vijaykumar / A.Locke / V.Reddy, Heart Rhythm 2010

V.Reddy et al Heart Rhythm (accepted)
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**Spatially Accurate Lesion Tracking (SALT)**

![Image of SALT](image1.png)

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

**Additional Ablation Required after the Initial Circumferential Lesion Set**

![Bar chart showing additional ablation](image2.png)

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

**Pepper to Identify Gaps**

![Image of Pepper](image3.png)

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

**Effect of SALT on Procedural Parameters**

![Graph showing procedural parameters](image4.png)

R.Vijaykumar / A.Locke / V.Reddy, Heart Rhythm 2010
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Effect of SALT on Procedural Parameters

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Can Pace-Capture Facilitate Ablation?

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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:
  – 1st Efficacy:
    • 12-mo AF/AT free rate off AADs
  – 1st Safety: Procedure-related events
  – Secondary Endpoints:
    • Number of gaps after encircling lesions
    • Total duration of RF Energy required
    • Time to achieve PV isolation

Follow-Up 12-month
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Pepper vs Force-Pepper

In Vivo Visually-Guided Spot Ablation

In Vivo Visually-Guided A.Flutter Ablation

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

In Vivo Visually-Guided A.Flutter Ablation

V.Reddy / P.Neuzil (manuscript in preparation)
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)
## How can we improve lesion formation?

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2. Lesion Indexing
3. Lesion Validation
   - Improving point-to-point ablation
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5. Remote Navigation
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## Cryoballoon Ablation

[Image of cryoballoon ablation]

## Clinical Outcome

<table>
<thead>
<tr>
<th>Study</th>
<th>N</th>
<th>Follow-Up</th>
<th>Paroxysmal</th>
<th>Persistent</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reddy et al, AHA 2005</td>
<td>20</td>
<td>12 mo</td>
<td>84%</td>
<td>—</td>
</tr>
<tr>
<td>Klein et al, Heart Rhythm 2008</td>
<td>21</td>
<td>6 mo</td>
<td>86%</td>
<td>—</td>
</tr>
<tr>
<td>Neumann et al, JACC 2008</td>
<td>293 / 53</td>
<td>12 mo</td>
<td>74%</td>
<td>42%</td>
</tr>
<tr>
<td>Linhart et al, HRS 2008</td>
<td>20</td>
<td>3 mo</td>
<td>50%</td>
<td>—</td>
</tr>
<tr>
<td>VanBelle et al, Cardiosim 2008</td>
<td>100</td>
<td>12 mo</td>
<td>64%</td>
<td>—</td>
</tr>
<tr>
<td>Kang et al, GCN 2008</td>
<td>28 / 12</td>
<td>8.8 mo</td>
<td>43%</td>
<td>42%</td>
</tr>
<tr>
<td>Packer et al, STOP-AF</td>
<td>163</td>
<td>12 mo</td>
<td>69.9%</td>
<td>—</td>
</tr>
</tbody>
</table>

## STOP-AF US IDE Trial

[Graph showing treatment success]

- **CRYO**: 69.9% (114/163)
- **DRUG Rx**: 7.3% (6/82)

P < 0.001

Packer et al, ACC, 2010
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STOP-AF: Success by Analysis Method

<table>
<thead>
<tr>
<th>Analysis Method</th>
<th>On / Off Drug</th>
<th>Single Ablation</th>
<th>On-Treatment Analysis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Intention to Treat</td>
<td>n = 114 (69.9%)</td>
<td>n = 20 (12.2%)</td>
<td>n = 88 (50.1%)</td>
</tr>
<tr>
<td>p &lt; 0.001</td>
<td>Absolute Δ 62.6%</td>
<td></td>
<td></td>
</tr>
<tr>
<td>n = 6 (7.3%)</td>
<td>p &lt; 0.001</td>
<td>Absolute Δ 56.6%</td>
<td>9%</td>
</tr>
<tr>
<td>Success Rate (%)</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

STOP-AF: Adverse Events

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

STOP-AF: Problems with the Cryoballoon

- Efficacy: Chronic PVI
- Safety Considerations
  - Tamponade
  - Stroke
  - Phrenic Nerve Paralysis
  - Pulmonary Vein Stenosis

What if there is a gap??
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What if there is a gap??

Pulldown: Effect on Balloon Temp

Where are the chronic breakthroughs?

STOP-AF: Problems with the Cryoballoon

- Efficacy: Chronic PVI
- Safety Considerations
  - Tamponade
  - Stroke
  - Phrenic Nerve Paralysis
  - Pulmonary Vein Stenosis
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Minimizing Phrenic Nerve Injury

- Pacing Catheter in SVC
- Cryoballoon Catheter at RSPV ostium

Imaging the Phrenic Nerve?


Which patients with PN Injury?


Why PV Stenosis after cryoballoon ablation?

- Courtesy of B.Schumacher
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Why PV Stenosis after cryoballoon ablation?

- PV Ostial Position
- Deep Venous Position

How can we improve lesion formation?

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Visually-Guided Ablation

- Aiming Beam
- "Static" Blood in LSPV

Pre-Clinical Evaluation

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

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**In vivo Visually-Guided Ablation**

**Pretreatment PV Sizes**

<table>
<thead>
<tr>
<th>PV</th>
<th>Mean ± SD</th>
<th>Min, Max</th>
</tr>
</thead>
<tbody>
<tr>
<td>LSPV (mm)</td>
<td>19.9 ± 3.2</td>
<td>(15, 27)</td>
</tr>
<tr>
<td>LIPV (mm)</td>
<td>19.8 ± 3.3</td>
<td>(15, 30)</td>
</tr>
<tr>
<td>RSPV (mm)</td>
<td>22.7 ± 3.3</td>
<td>(17, 30)</td>
</tr>
<tr>
<td>RIPV (mm)</td>
<td>20.8 ± 3.3</td>
<td>(13, 26)</td>
</tr>
<tr>
<td>LCPV (mm)</td>
<td>27.8 ± 5.8</td>
<td>(20, 35)</td>
</tr>
<tr>
<td>RCPV (mm)</td>
<td>27.5 ± 0.7</td>
<td>(27, 28)</td>
</tr>
</tbody>
</table>

**Procedural Details**

<table>
<thead>
<tr>
<th>Procedure</th>
<th>Mean ± SD</th>
<th>Min, Max</th>
</tr>
</thead>
<tbody>
<tr>
<td>Procedure Time (hh:mm)</td>
<td>3:16 ± 0:38</td>
<td>(2:16, 4:32)</td>
</tr>
<tr>
<td>Fluoroscopy Time (min)</td>
<td>19 ± 10</td>
<td>(7, 64)</td>
</tr>
<tr>
<td>Ablation time (hh:mm)</td>
<td>1:40 ± 0:27</td>
<td>(0:46, 2:27)</td>
</tr>
</tbody>
</table>

**Safety**

- No Device Related Adverse Events
  - 1 occurrence new onset atrial flutter
- No clot, char or steam pops
- No PV stenosis
Is Visually-Guided ablation permanent?

- Study in Prague:
  - Ablation in 40 pts
  - EP study at 10 weeks in all patients (regardless of sxss)
  - 33 pts came for 2nd procedure at 11.1±0.9 wks
- Results:
  - 33 patients → 127 PVs
  - Persistent Isolation
  - 113/125 PVs (90%)

Correlation of PVI & Clinical Success

Model assumes: i) 4 PVs / pt, and ii) PVs are isolated individually.

How can we improve lesion formation?

1. Image-Guidance
2. Lesion Indexing
3. Lesion Validation
4. Contact Sensing Strategies
5. Remote Navigation
6. Cryo-Balloon
7. Visually-guided Laser Balloon
8. Curvilinear Catheters

Linear Ablation Technologies
What about Persistent AF?

Persistent AF: Catheter Ablation

Persistent AF: Why does ablation fail?
Current, Competing and Emerging Technologies in the Ablation of Atrial Fibrillation

Vivek Y. Reddy, MD

Atypical Flutter: Multielectrode Mapping

Propagation of CCW PMI AFL (250 ms)

EGMs at Anterior MV Annulus

Persistent AF Ablation: Outcome


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

Vivek Y. Reddy, MD

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