Contemporary Management of Atrial Fibrillation

November 9, 2021

We will get started shortly. Your lines are muted upon entry. This event will be recorded.
Welcome!

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- All participants are muted on entry
- Ask questions using the Q&A Box
- Please fill out the satisfaction survey
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PeaceHealth
Sacred Heart Medical Center

Continuing Medical Education
Contemporary Management of Atrial Fibrillation

November 9 | 6:00 pm - 7:30 pm PST

Moderator:
Sally Mack, MHA
Strategic Planning and Business Development Consultant, PeaceHealth

Presenters:
Sree Karanam, MD, FHRS
Electrophysiologist, PeaceHealth

Ashok Venkataraman, MD
Cardiothoracic Surgeon, PeaceHealth
Sree Karanam, MD, FHRS
Electrophysiologist, PeaceHealth

Ashok Venkataraman, MD
Cardiothoracic Surgeon, PeaceHealth
Atrial Fibrillation: An update on management

Sree Karanam, MD FHRS
Oregon Heart and Vascular Institute
Disclosures: none
Atrial Fibrillation

- Most common arrhythmia in clinical practice.
- Increasing Incidence and prevalence with increasing age.
- Often difficult to treat. Significant morbidity from symptoms.
- Two fold increase in mortality and five fold increase in risk of stroke.
Definitions

- **Paroxysmal**: Recurrent AF that terminates spontaneously or with treatment. Lasts < 7 days.
- **Persistent**: AF lasting longer than 7 days
- **Long standing persistent**: Continuous AF of 12 months duration or longer.
- **Permanent AF**
AF: categories

- Valvular: Rheumatic mitral stenosis, hx of mitral valve repair, prosthetic valves.
- Non-valvular: accounts for 90% of clinical Afib.
- HCM and congenital heart disease.
- Non-cardiac causes: Acute PE, hyperthyroidism, WPW.
<table>
<thead>
<tr>
<th>Risk Factors</th>
<th>Relative Risk</th>
</tr>
</thead>
<tbody>
<tr>
<td>Previous stroke</td>
<td>2.5</td>
</tr>
<tr>
<td>Diabetes mellitus</td>
<td>1.7</td>
</tr>
<tr>
<td>Hypertension</td>
<td>1.6</td>
</tr>
<tr>
<td>Heart Failure</td>
<td>1.4</td>
</tr>
<tr>
<td>Age&gt;75 yrs</td>
<td>1.4</td>
</tr>
</tbody>
</table>
AF: Risk of Stroke

- C hf: 1
- H ypertension: 1
- A ge>75 yrs: 1
- D iabetes: 1
- S troke: 2

CHADS$_2$ score: 0-1: ASA.
1-2: ASA or Warfarin and > 2: Warfarin
AF: Assessing stroke risk

- CHADS VASc score.
- Better risk stratification for low risk pts.
- 0: No anticoagulation
- 1: Aspirin or VKA/NOACs
- 2 or greater: VKA or NOACs
AF: stroke prevention.

- Valvular Afib: Warfarin.
- HCM and fib: Warfarin or NOACs.
- Non valvular fib: Use CHADS VASc or ATRIA scores.
- CHADS VASc of 2.0 or higher: NOACs or Warfarin.
AF: stroke prevention.

- Achilles heal of NOACs: poor compliance. 30% of pts stop the drug at 2 year f/u.
- High discontinuation rates in pivotal clinical trials. ARISTOTLE: 25% and RELY: 21%
- Annual bleeding risk: 2-3% with NOACs. Higher in elderly patients.
AF: stroke prevention.

- Significant reduction in hemorrhagic and disabling strokes and CV mortality.
- Reasonable alternative in its who cannot be anti-coagulated/high bleeding risk.
Patient-Level Meta-Analysis
PROTECT AF and PREVAIL 5 years

<table>
<thead>
<tr>
<th>Event</th>
<th>HR</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Efficacy</td>
<td>0.82</td>
<td>0.3</td>
</tr>
<tr>
<td>All stroke or SE</td>
<td>0.96</td>
<td>0.9</td>
</tr>
<tr>
<td>Ischemic stroke or SE</td>
<td>1.7</td>
<td>0.08</td>
</tr>
<tr>
<td>Hemorrhagic stroke</td>
<td>0.2</td>
<td>0.0022</td>
</tr>
<tr>
<td>Ischemic stroke or SE &gt;7 days</td>
<td>1.4</td>
<td>0.3</td>
</tr>
<tr>
<td>CV/unexplained death</td>
<td>0.59</td>
<td>0.03</td>
</tr>
<tr>
<td>All-cause death</td>
<td>0.73</td>
<td>0.04</td>
</tr>
<tr>
<td>Major bleed, all</td>
<td>0.91</td>
<td>0.6</td>
</tr>
<tr>
<td>Major bleeding, non procedure-related</td>
<td>0.48</td>
<td>0.0003</td>
</tr>
</tbody>
</table>

Hazard Ratio (95% CI)
Results
WATCHMAN Comparable to Warfarin for Ischemic Stroke

- Untreated AF
- Treated with Warfarin
- WATCHMAN Arm

Ischemic Stroke Risk (events per 100 pt-ys)

Baseline CHA₂DS₂-VASc Score

Graph showing the relationship between baseline CHA₂DS₂-VASc score and ischemic stroke risk.
Patient-Level Meta-Analysis
WATCHMAN Superior for Hemorrhagic Stroke, CV Death, All-Cause Death, Post-procedure Bleeding

<table>
<thead>
<tr>
<th>Outcome</th>
<th>HR</th>
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<td>0.48</td>
<td>0.0003</td>
</tr>
</tbody>
</table>
PINNACLE FLX Trial met primary safety and efficacy endpoints and demonstrated high procedural success and DOAC discontinuation at 45 day follow-up.¹

- **0.5%** Event rate
  - Met Primary Safety Endpoint

- **100%** LAA Closure
  - Met Primary Efficacy Endpoint

- **98.8%** Procedural Success

- **96.2%** DOAC Discontinued at 45 day follow-up

---

¹ The WATCHMAN FLX™ Left Atrial Appendage Closure Device is an investigational device and is not available for sale in the U.S.
Primary Safety Endpoint met with low 0.5% event rate

Performance Goal = 4.21%

0.5% Ischemic Stroke (2/400)
0% All-cause Death
0% Pericardial Effusions Requiring Open Cardiac Surgery
0% Device Embolization

*Based on PREVAIL and CAP2 combined rate plus a clinically relevant delta

*Occurrence of one of the following events between the time of implant and within 7 days following the procedure or by hospital discharge, whichever is later: all-cause death, ischemic stroke, systemic embolism, or device or procedure related events requiring open cardiac surgery or major endovascular intervention.
**Primary Safety Endpoint in Perspective**

*Major Procedural Complications within 7 Days Across Trials*

Low event rates in the PINNACLE FLX trial demonstrated the added safety of the WATCHMAN FLX™ device, when compared to the consistently low rates observed in previous WATCHMAN trials.
Primary Efficacy Endpoint met with 100% Effective LAA Closure at 12 months

Primary Effectiveness Endpoint:

100% of Subjects Demonstrated Effective LAA Closure at 12 Months

(P<0.0001)**

Performance Goal = 97.0%**

* LAA closure at 12 months (defined as any per-device flow with jet size ≤ 5mm per core laboratory-assessed TEE)
** Based on PREVAIL and CAP2 combined rate plus a clinically relevant delta
98.8% Procedure Success

PINNACLE FLX showed procedure success* consistent with recent WATCHMAN studies

*Procedure success defined as successful delivery and release of a WATCHMAN FLX device into the LAA
Reported N values on this slide are those of attempted implants. All cancelled procedures are excluded from this analysis

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AF management

AF: Rate and Rhythm Control

- In most patients
  - Rate control
  - Symptoms despite rate control
    - Failure of rate control
      - Tachycardia mediated cardiomyopathy
        - Younger age
        - 1st AF episode
        - Patient preference
  - Permanent AF
    - Rate control
    - AVN ablation?
AF management: Rhythm control

No structural heart disease

Class I

Class 1c
Flecainide
Propafenone
Class III
Sotalol
Dronedarone
Dofetilide

Drugs

Amio

Ablation

January et al 2014 AHA/ACC/HRS Atrial Fibrillation Guidelines
AF management

Cardioversion
Pharmacologic

<table>
<thead>
<tr>
<th>AAD Class</th>
<th>Class 1c</th>
<th>Class III</th>
<th>Class III</th>
</tr>
</thead>
<tbody>
<tr>
<td>Drug</td>
<td>Pill in the pocket</td>
<td>Flecainide (200 – 300 mg)</td>
<td>Ibutilide I.V.</td>
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<tr>
<td></td>
<td>Propafenone (450 – 600 mg)</td>
<td>PO</td>
<td></td>
</tr>
<tr>
<td>Potential complications</td>
<td>Hypotension</td>
<td>Bradycardia</td>
<td>Torsades de Pointes</td>
</tr>
<tr>
<td></td>
<td>1:1 A flutter</td>
<td>VT</td>
<td></td>
</tr>
<tr>
<td>Precautions</td>
<td>C/I structural HD</td>
<td>First attempt in monitored setting</td>
<td>C/I if QT prolonged, hypoK, hypoMg</td>
</tr>
<tr>
<td></td>
<td>CCB or BB ≥30 min before 1c</td>
<td>Monitor for ≥4h</td>
<td>IV Mg prior to ibutilide</td>
</tr>
</tbody>
</table>

Precautions:
- C/I structural HD
- First attempt in monitored setting
- CCB or BB ≥30 min before 1c
- C/I if QT prolonged, hypoK, hypoMg
- Monitor for ≥4h
- IV Mg prior to ibutilide
AF management

- No structural heart disease
  - Flecaïnide
  - Propafenone
  - Sotalol
  - Dronedarone
  - Dofetilide
  - Amiodarone
  - Class I
  - Ablation
  - Only paroxysmal symptomatic AF
AF management

Structural heart disease

Contraindicated
Class 1c

CAD, MI

Sotalol
Dofetilide
Dronedarone

Ablation

LVEF

Dofetilide
Amiodarone

Amiodarone
Cumulative Mortality from Any Cause in the Rhythm-Control Group and the Rate-Control Group

Kaplan-Meier Estimates of Death from Cardiovascular Causes (Primary Outcome)

![Graph showing survival rates with rate control and rhythm control over months of follow-up.]

<table>
<thead>
<tr>
<th>Months of Follow-up</th>
<th>Rhythm control</th>
<th>Rate control</th>
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</thead>
<tbody>
<tr>
<td>0</td>
<td>593</td>
<td>604</td>
</tr>
<tr>
<td>12</td>
<td>514</td>
<td>521</td>
</tr>
<tr>
<td>24</td>
<td>378</td>
<td>381</td>
</tr>
<tr>
<td>36</td>
<td>228</td>
<td>219</td>
</tr>
<tr>
<td>48</td>
<td>82</td>
<td>69</td>
</tr>
</tbody>
</table>

P = 0.59

AF management

Indications for Catheter Ablation

Symptomatic AF

- Paroxysmal
  - AAD
    - Class I
  - AAD
    - Class IIa

- Persistent
  - AAD
    - Class IIa
  - AAD
    - Class IIb

- Long standing persistent (>12 mon)
  - AAD
    - Class IIb
  - Intolerant or refractory to ≥ 1 AAD

Catheter ablation
Indications for AF Ablation

- Symptomatic AF refractory or intolerant to at least one Class I or III antiarrhythmic drug.
- In rare situations, it may be appropriate to consider ablation as first line therapy.
- Selected symptomatic patients with heart failure and/or reduced ejection fraction.
AF mechanisms

- Multiple Wavelet Hypothesis (Moe et al) 1980.
- Focal Triggers (Haissaguerre et al) 1994. First successful AF ablation targeting Pulmonary veins, SVC.
- Muscular sleeves extending into the veins.
- P cells, transitional and Purkinje cells have been localized to the myocardial sleeves.
- Spontaneous electrical activity.
AF mechanisms.

- Autonomic nervous system and cholinergic influence.
- Triggered firing within the veins upon stimulation of the ganglionated plexi.
- Focal triggers can result in sustained high frequency reentrant AF drivers (rotors) within the LA myocardium.
- Wavebreak and fractionation.
- LA substrates: Posterior LA, Septum etc.
AF mechanisms

[Diagram showing various mechanisms with labels such as LSPV, RSPV, SVC, and the ligament of Marshall]
AF ablation

Pre-procedure work-up:

- CTA to verify PV and LA anatomy and LV function (not mandatory).
- Pre-procedure TEE to look for LAA thrombi in selected high risk patients.
- Coumadin/NOACs for at least one month pre-ablation.
- Ablation performed with full dose anticoagulation and INRs in the 2-3.5 range.
- Intra-procedure ICE imaging for transeptal LA access and monitoring for complications.
- PV isolation: RF or cryoenergy
Which patients? Which techniques?

AF presentation
- paroxysmal
- persistent
- permanent

Ablation target(s)
- trigger
- substrate
- ANS

“Electrical” vs. “anatomic” approaches
The Trigger approach for focal AF

Segmental Ostial Ablation
Ablation strategies

- Cornerstone of AF ablation is complete pulmonary vein isolation.
- For persistent and chronic AF, additional lines are necessary to modify the LA substrate (roof line, mitral isthmus line, CT isthmus line for Afl).
- Non PV triggers, CFAE etc.
- Ganglionated plexi (GP) ablation.
Complex Fractionated Electrograms

Organized E-gram

CFE Mean Map

More Complex E-gram
Fractionation Mapping

- CFE Mean: Average activation time between deflections
- CFE Standard Deviation: Deflection Regularity
Substrate modification for persistent / permanent AF

Nademane et al. K JACC. 2004 2:43:2054-6
Substrate modification for paroxysmal AF

Substrate modification for persistent / permanent AF

- Anatomic approach

- Electro-anatomic approach

- PVI ± Left mitral isthmus ± Left atria roof line
  - Haissaguerre et al. JCE 2005;16:1138-47
  - Fassini et al. JCE 2005;16:1150-6
Original Article

Approaches to Catheter Ablation for Persistent Atrial Fibrillation

Atul Verma, M.D., Chen-yang Jiang, M.D., Timothy R. Betts, M.D., M.B., Ch.B., Jian Chen, M.D., Isabel Deisenhofer, M.D., Roberto Mantovan, M.D., Ph.D., Laurent Macle, M.D., Carlos A. Morillo, M.D., Wilhelm Haverkamp, M.D., Ph.D., Rukshen Weerasooriya, M.D., Jean-Paul Albenque, M.D., Stefano Nardi, M.D., Endri Menardi, M.D., Paul Novak, M.D., Prashanthan Sanders, M.B., B.S., Ph.D., for the STAR AF II Investigators

N Engl J Med
Volume 372(19):1812-1822
May 7, 2015
Study Overview

• In patients with persistent atrial fibrillation, rates of recurrent atrial fibrillation at 18 months were not significantly different when linear ablation or ablation of complex fractionated electrograms was performed along with pulmonary-vein isolation.
Freedom from Atrial Fibrillation.

P = 0.15 for the overall comparison, by the log-rank test.

No. at Risk

<table>
<thead>
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<th>Treatment</th>
<th>0</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
<th>7</th>
<th>8</th>
<th>9</th>
<th>10</th>
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<th>14</th>
<th>15</th>
<th>16</th>
<th>17</th>
<th>18</th>
<th>19</th>
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<tbody>
<tr>
<td>Pulmonary-vein isolation</td>
<td>61</td>
<td>60</td>
<td>50</td>
<td>41</td>
<td>36</td>
<td>23</td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Isolation plus electrograms</td>
<td>244</td>
<td>242</td>
<td>161</td>
<td>137</td>
<td>124</td>
<td>72</td>
<td></td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Isolation plus lines</td>
<td>244</td>
<td>240</td>
<td>152</td>
<td>133</td>
<td>115</td>
<td>57</td>
<td></td>
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</tbody>
</table>

Conclusions

- Among patients with persistent atrial fibrillation, we found no reduction in the rate of recurrent atrial fibrillation when either linear ablation or ablation of complex fractionated electrograms was performed in addition to pulmonary-vein isolation.
Catheter ablation for persistent & permanent AF: Results

- >90% Ouyang et al. Circulation 2005;112:3038-48
- ≈70% Fassini et al. JCE 2005;16:1150-6
- >85% Haissaguerre et al. JCE 2005;16:1138-47
- ≈70% Willems et al. Eur Heart J. 2006;16
Conclusions

• Catheter ablation for lone paroxysmal AF
  – high success rates
  – acceptable complication rates
  → good indication after a class I AA drug failure

• Catheter ablation for persistent/permanent AF
  – more difficult - lower success rates
  – higher complication rates
  → more controversial for “lone” AF
  → for patients who really need Sinus rhythm
Patient Randomization

Subjects 2204

Ablation Therapy 1108
- Ablated 1006 (90.8%)
  - repeat ablation 215 (19.4%)
- Not ablated 102 (9.2%)
- Completed FU 1002 (90.4%) 48.9 mo

Drug Therapy 1096
- Drug Treated 1092 (99.6%)
  - rhythm control 953 (87.2%)
  - rate control only 126 (11.5%)
- Cross Over Ablated 301 (27.5%)
- Completed FU 966 (88%) 48.2 mo
<table>
<thead>
<tr>
<th>AF Type</th>
<th>Ablation</th>
<th>Drug Therapy</th>
</tr>
</thead>
<tbody>
<tr>
<td>Paroxysmal</td>
<td>42.4%</td>
<td>43.5%</td>
</tr>
<tr>
<td>Persistent</td>
<td>47.3%</td>
<td>47.3%</td>
</tr>
<tr>
<td>Longstanding Persistent</td>
<td>10.3%</td>
<td>9.2%</td>
</tr>
<tr>
<td>Years since onset of AF [Median (Q1,Q3)]</td>
<td>1.1 (0.3, 4.1)</td>
<td>1.1 (0.3, 3.9)</td>
</tr>
<tr>
<td>CCS Severity of AF</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Class 0-1</td>
<td>34.6%</td>
<td>26.7%</td>
</tr>
<tr>
<td>Class 2</td>
<td>31.8%</td>
<td>32.4%</td>
</tr>
<tr>
<td>Class 3-4</td>
<td>43.5%</td>
<td>41.0%</td>
</tr>
<tr>
<td>Prior hospitalization for AF</td>
<td>40.6%</td>
<td>38.8%</td>
</tr>
</tbody>
</table>
Primary Endpoint (Death, Disabling Stroke, Serious Bleeding, or Cardiac Arrest) (ITT)

Ablation vs. Drug
Hazard ratio: 0.86 (95% CI, 0.65–1.15)
P = 0.303

Number at risk
- Drug: 1096, 1036, 1006, 970, 908, 880, 763, 652, 578, 499, 418, 312
- Ablation: 1108, 1045, 1021, 996, 915, 793, 700, 614, 535, 432, 309

Event rate (%)
- Months since randomization
Estimates of All-Cause Mortality Risk (ITT)

Ablation vs. Drug
Hazard ratio: 0.85 (95% CI, 0.60–1.21)
P=0.377

Mortality rate (%)

Months since randomization

Number at risk
Drug  Ablation
0  1096  1108
6  1046  1058
12  1023  1035
18  992   1013
24  903   933
30  783   814
36  679   724
42  606   632
48  527   555
54  445   455
60  334   332
## Primary and Secondary Outcomes (Treatment Received)*

<table>
<thead>
<tr>
<th></th>
<th>Ablation (N = 1307)</th>
<th>Drug (N = 897)</th>
<th>Hazard Ratio (95% CI)</th>
<th>P-Value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Primary Outcome</strong></td>
<td>92 (7.0%)</td>
<td>98 (10.9%)</td>
<td>0.67 (0.50, 0.89)</td>
<td>0.006</td>
</tr>
<tr>
<td><strong>Secondary Outcomes</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>All-cause mortality</td>
<td>58 (4.4%)</td>
<td>67 (7.5%)</td>
<td>0.60 (0.42, 0.86)</td>
<td>0.005</td>
</tr>
<tr>
<td>Death or CV hospitalization</td>
<td>538 (41.2%)</td>
<td>672 (74.9%)</td>
<td>0.83 (0.74, 0.94)</td>
<td>0.002</td>
</tr>
</tbody>
</table>

*Note: The table above represents outcomes from a treatment study. The primary outcome shows a significant difference between ablation and drug therapy, with a hazard ratio of 0.67 (0.50, 0.89) and a p-value of 0.006. Secondary outcomes include all-cause mortality and death or CV hospitalization, with respective hazard ratios and p-values indicated.
Primary Endpoint (Death, Disabling Stroke, Serious Bleeding, or Cardiac Arrest (Per Protocol))

Ablation vs. Drug
Hazard ratio: 0.73 (95% CI, 0.54–0.99)
P=0.046
## Adverse Events in CABANA

<table>
<thead>
<tr>
<th>Event</th>
<th>Ablation n = 1006</th>
<th>Pts Receiving Drug n = 1092</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Event</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Catheter Insertion</td>
<td>39 (3.9)</td>
<td>17 (1.6)</td>
</tr>
<tr>
<td>Hematoma</td>
<td>23 (2.3)</td>
<td>3 (0.3)</td>
</tr>
<tr>
<td>Pseudo aneurysm</td>
<td>11 (1.1)</td>
<td>9 (0.8)</td>
</tr>
<tr>
<td>Atrial venous fistula</td>
<td>4 (0.4)</td>
<td>0</td>
</tr>
<tr>
<td>Pneumothorax</td>
<td>1 (0.1)</td>
<td>0</td>
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<tr>
<td>Sepsis</td>
<td>1 (0.1)</td>
<td>0.1</td>
</tr>
<tr>
<td>DVT</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Pulmonary embolus</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Catheter Manipulation Within the Heart</td>
<td>34 (3.4)</td>
<td>7 (0.6)</td>
</tr>
<tr>
<td>Pericardial effusion not requiring intervention</td>
<td>22 (2.2)</td>
<td>3 (0.3)</td>
</tr>
<tr>
<td>Cardiac tamponade with perforation</td>
<td>8 (0.8)</td>
<td>0.3</td>
</tr>
<tr>
<td>TIA</td>
<td>3 (0.3)</td>
<td>0</td>
</tr>
<tr>
<td>Coronary occlusion</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Myocardial infarction</td>
<td>1 (0.1)</td>
<td>0</td>
</tr>
<tr>
<td>Complete heart block</td>
<td>0</td>
<td>0.1</td>
</tr>
<tr>
<td>Valvular damage</td>
<td>0</td>
<td>1 (0.1)</td>
</tr>
<tr>
<td>Ablation-related Events</td>
<td>18 (1.8)</td>
<td>0</td>
</tr>
<tr>
<td>Severe pericardial chest pain</td>
<td>11 (1.1)</td>
<td>0</td>
</tr>
<tr>
<td>Esophageal ulcer</td>
<td>5 (0.5)</td>
<td>0</td>
</tr>
<tr>
<td>Pulmonary Vein Stenosis &gt; 75%</td>
<td>1 (0.1)</td>
<td>0</td>
</tr>
<tr>
<td>Phrenic nerve injury</td>
<td>1 (0.1)</td>
<td>0.3</td>
</tr>
<tr>
<td>Atrial esophageal fistula</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Medication-related Events</td>
<td>0</td>
<td>0.1</td>
</tr>
<tr>
<td>Heparin induced bleeding</td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>

* n (%) = number (percent) of patients who reported drug-related adverse event. Percent is calculated among all patients that have received drug.
Conclusion of the CABANA Trial

• Ablation did not produce a significant reduction in the primary endpoint and all-cause mortality.
• The results were affected by cross-overs in both directions and lower than expected event rates.
• Ablation significantly reduced mortality or CV hospitalization by 17% compared to drug therapy.
• There also was a significant 47% reduction in recurrent AF with ablation compared to drug therapy.
• A 33% reduction in the primary endpoint and 40% mortality risk reduction was present when patients actually underwent ablation (treatment received).
• Ablation is an acceptable treatment strategy for treating AF with low adverse event rates even in higher risk patients.
Catheter Ablation: Don’ts

- Don’t ablate patients who cannot be anticoagulated
- Primary indication for ablation should not be obviating the need for OAC
AF ablation: Complications

- Multicenter prospective registry of 1,011 pts with a mean age of 58 yrs.
- Complications reported in 40 pts (3.9%)
- 12 (1.2%) : peripheral vascular
- 8 (0.8%) : pericardial effusion
- 6 (0.6%): Tamponade
- 5 (0.5%): cerebral embolism/stroke
- 4 (0.4%): PV stenosis > 50%

# AF Ablation

## Risks of Atrial Fibrillation Ablation

**16,309 Patients**

<table>
<thead>
<tr>
<th>Type of complication</th>
<th>Rate (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Death</td>
<td>0.15</td>
</tr>
<tr>
<td>Tamponade</td>
<td><strong>1.31</strong></td>
</tr>
<tr>
<td>Permanent diaphragmatic paralysis</td>
<td>0.17</td>
</tr>
<tr>
<td>Pulmonary veins stenoses requiring intervention</td>
<td>0.29</td>
</tr>
</tbody>
</table>
AF ablation complications

Manifestations of Atrial Esophageal Fistulae

Typically 1-4 weeks after ablation

- Fever/chills
- Esophageal symptoms
- Stroke
- GI bleeding
- Asymptomatic before major event
AF ablation complications

Approach to Managing Possible Esophageal-Atrial Fistula
Refer Immediately

- Esophageal Sxs
- CNS symptoms
- Fever

- CT/MR
- Avoid endoscopy
- Surgery
Follow-up post ablation.

- Early recurrence of AF or AT common during first 3 months of follow-up, in up to 45% of patients. This subsides spontaneously in over 60% of patients.
- Asymptomatic AF is common.
- Patients are maintained on AADs for the first few months post ablation.
- Repeat procedures in 20-30% of patients for AT or AF.
Conclusions:

- Symptom control, QOL and stroke prevention.
- Use NOACs or Warfarin.
- Consider LA appendage occlusion or exclusion as an alternative.
- Catheter ablation for Paroxysmal AF
- Convergent ablation for long standing persistent AF
Concept of Hybrid AF Ablation (Convergent Procedure – Epicardial Ablation + Endocardial Ablation)
AF: A Serious and Growing Problem

Atrial Fibrillation is an irregular heartbeat (or arrhythmia) that affects more than 33 million people worldwide.\(^1\)

<table>
<thead>
<tr>
<th>5x</th>
<th>Risk of stroke(^3)</th>
</tr>
</thead>
<tbody>
<tr>
<td>&gt;5x</td>
<td>Higher risk of heart failure(^4)</td>
</tr>
<tr>
<td>46%</td>
<td>Greater risk of all-cause mortality(^4)</td>
</tr>
</tbody>
</table>

More cardiac complications\(^5\)

Approximately 1.2 million Afib diagnoses annually in the US.\(^2\)

Consequences of AF:
- Stroke, heart failure (structural remodeling)
- Impact on QOL and normal daily activities
AF: Atrial Fibrillation Is Progressive

- AF burden is associated with atrial remodeling and development of atrial fibrosis
- Structural and functional atrial changes eventually lead to the development, maintenance, and progression of AF
AF: Significant Patient Burden

- Up to 47% reduction in quality of life\textsuperscript{7-11}
- Heightened Anxiety about medications\textsuperscript{12}
- Burnout from frequent follow-up appointments\textsuperscript{13}

- Decreased general and mental health\textsuperscript{14}
- 10 Outpatient hospital visits and
- >50 physician encounters per year\textsuperscript{15}
- Decreased Cognitive Function\textsuperscript{5,16,17}
AF: Mortality Impact Underestimated\textsuperscript{18,19}

<table>
<thead>
<tr>
<th>Type of Cancer</th>
<th>Survival Rate Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pancreas</td>
<td>4.1</td>
</tr>
<tr>
<td>Brain and CMS</td>
<td>7.0</td>
</tr>
<tr>
<td>Lung and Bronchus</td>
<td>14.9</td>
</tr>
<tr>
<td>Stomach</td>
<td>23.9</td>
</tr>
<tr>
<td>Ovary</td>
<td>27.5</td>
</tr>
<tr>
<td>Atrial Fibrillation</td>
<td>51.2</td>
</tr>
<tr>
<td>Hodgkin Lymphoma</td>
<td>52.4</td>
</tr>
<tr>
<td>Colon</td>
<td>62.6</td>
</tr>
<tr>
<td>Kidney and Renal Pelvis</td>
<td>64.5</td>
</tr>
<tr>
<td>Chronic Lymphocytic Leukemia</td>
<td>73.4</td>
</tr>
<tr>
<td>Melanoma</td>
<td>88.4</td>
</tr>
<tr>
<td>Breast</td>
<td>88.9</td>
</tr>
<tr>
<td>Prostate</td>
<td>99.2</td>
</tr>
</tbody>
</table>

Medicare patients over age 65 within 5 years of Afib diagnosis.
## Current AF Treatment Options

<table>
<thead>
<tr>
<th>Therapy Type</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Medication</td>
<td>oral anticoagulants, rate and rhythm control</td>
</tr>
<tr>
<td>Cardioversion</td>
<td>electrical and pharmacological</td>
</tr>
<tr>
<td>Catheter Ablation</td>
<td>pulmonary vein isolation (PVI)</td>
</tr>
<tr>
<td>Hybrid AF Therapy Convergent</td>
<td>multispecialty epicardial/endocardial approach</td>
</tr>
<tr>
<td>Left Atrial Appendage Management</td>
<td>surgical/epicardial/endocardial</td>
</tr>
<tr>
<td>Surgical Ablation</td>
<td>concomitant Cox MAZE IV</td>
</tr>
<tr>
<td>Device-Based Therapy</td>
<td>pacemaker, implantable loop recorder</td>
</tr>
</tbody>
</table>
Hybrid AF Therapy Convergent Procedure

The Hybrid AF Convergent procedure combines endocardial and epicardial ablation to achieve a more comprehensive intervention while minimizing risk of esophageal injury.

Post Epicardial Ablation

The epicardial ablation is conducted by a cardiac surgeon via subxiphoid access to the pericardium.

Post Epicardial & Endocardial Ablation

The endocardial procedure is conducted by an electrophysiologist via percutaneous access.
Hybrid AF™ Therapy Convergent

Combines minimally invasive techniques and technologies of EP and CT

- Epicardial Ablation Procedure:
  - CT surgeon complements PVI by providing a comprehensive posterior wall ablation
  - Minimally invasive subxiphoid access
  - RF energy applied away from esophagus
  - Direct endoscopic visualization
- Endocardial Ablation Procedure:
  - EP procedure done same day or staged
  - EP maps identify regions requiring additional ablation
  - Completes the lesion set and the Hybrid AF procedure with pulmonary vein isolation

Posterior view of the left atrium & pulmonary veins
Electrical Activity Post Hybrid AF Therapy Convergent

Source: Dr. David DeLurgio
Hybrid AF Ablation - Convergent

Hybrid AF Convergent US

Total Number of Hybrid AF Procedures Performed through 2020 = Over 10,000
Conclusions for Long-Standing Persistent AF: The totality of evidence from the randomized CONVERGE clinical trial and real-world clinical experience demonstrates there is a reasonable assurance of safety and effectiveness to support the use of the Epi-Sense device to treat patients presenting with symptomatic drug refractory long-standing persistent atrial fibrillation.
**Hybrid AF CONVERGE IDE Trial: Outcomes**

Based on 7-day continuous rhythm monitoring at 18 months post procedure

- **More than 2x as effective at stopping AA** (vs endocardial RF ablation alone)
- **Patients are 2x more likely to no longer need AF medication** (vs endocardial RF ablation alone)
- **≥90% less time in AF** for most patients at 1 year
- **2 trigger areas targeted** where atrial fibrillation begins

People in the Hybrid AF arm report feeling better, both physically and emotionally.

Procedure is safe and effective.

---

Data based on the post-hoc analysis of 592 standing persistent AF sub-groups (N=65)
E2a-Sense® System Summary of Safety and Effectiveness data: PMAF200002
AA: Atrial arrhythmia
Hybrid AF CONVERGE IDE Trial: Outcomes\textsuperscript{2,3}

Long-Standing Persistent

12-Month Outcomes

<table>
<thead>
<tr>
<th></th>
<th>Hybrid Convergent</th>
<th>Endocardial ablation alone</th>
</tr>
</thead>
<tbody>
<tr>
<td>Freedom from atrial arrhythmia absent AADs</td>
<td>52.6 (26.7%)</td>
<td>25.9</td>
</tr>
<tr>
<td>Freedom from atrial arrhythmia absent new/increased dose of failed AADs</td>
<td>65.8 (28.8%)</td>
<td>37.0</td>
</tr>
<tr>
<td>Freedom from atrial arrhythmia regardless of AADs</td>
<td>73.7 (29.2%)</td>
<td>44.4</td>
</tr>
</tbody>
</table>

18-Month Outcomes

<table>
<thead>
<tr>
<th></th>
<th>Hybrid Convergent</th>
<th>Endocardial ablation alone</th>
</tr>
</thead>
<tbody>
<tr>
<td>Freedom from atrial arrhythmia absent AADs</td>
<td>47.4 (25.2%)</td>
<td>22.2</td>
</tr>
<tr>
<td>Freedom from atrial arrhythmia absent new/increased dose of failed AADs</td>
<td>60.5 (34.6%)</td>
<td>25.9</td>
</tr>
<tr>
<td>Freedom from atrial arrhythmia regardless of AADs</td>
<td>68.4 (35.1%)</td>
<td>33.3</td>
</tr>
</tbody>
</table>

Freedom from atrial arrhythmia with and/or without AADs was notably higher with Hybrid AF Convergent Vs endocardial ablation alone, and sustained through 18 months (7-day Holter)

Data based on the post-hoc analysis of long-standing persistent AF sub-groups (N=65)

IFU for EPI-Sense® Guided Ablation System Data: PMA# P200002
Hybrid AF CONVERGE IDE Trial: Outcomes\textsuperscript{2,3}

Long-Standing Persistent

A total of 71% Hybrid Convergent patients vs 41% endocardial ablation patients had freedom from cardioversion through 12 months.

Data based on the post-hoc analysis of long-standing persistent AF sub-groups (N=65).
IFU for EPI-Sense® Guided Coagulation System Data: PNA# P200002

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Hybrid AF CONVERGE IDE Trial: Outcomes

Hybrid AF Convergent Arm AF Symptom Reduction Baseline to 12 Months

Baseline to 12 Months

<table>
<thead>
<tr>
<th>Symptom</th>
<th>Baseline (%)</th>
<th>12 Months (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Palpitations</td>
<td>76.3</td>
<td>18.4</td>
</tr>
<tr>
<td>Shortness of Breath at Rest</td>
<td>81.6</td>
<td>42.1</td>
</tr>
<tr>
<td>Shortness of Breath Physical Activity</td>
<td>86.8</td>
<td>73.7</td>
</tr>
<tr>
<td>Exercise Intolerance</td>
<td>89.5</td>
<td>55.3</td>
</tr>
<tr>
<td>Fatigue at Rest</td>
<td>78.9</td>
<td>34.2</td>
</tr>
<tr>
<td>Lightheadedness/Dizziness</td>
<td>71.1</td>
<td>23.7</td>
</tr>
<tr>
<td>Chest Pain or Pressure</td>
<td>50.0</td>
<td>21.1</td>
</tr>
</tbody>
</table>

Data based on the pooled analysis of long-standing persistent AF sub-groups (N=45).
PID for EP Gastro Gastro Copulation: System Date: Prioritizing-F2000202

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Advanced AF Patients
Most Prevalent and Most Difficult to Treat AF Population

<table>
<thead>
<tr>
<th>Paroxysmal</th>
<th>Persistent</th>
<th>Long-Standing Persistent</th>
</tr>
</thead>
<tbody>
<tr>
<td>30% of Patients</td>
<td>25% of Patients</td>
<td>45% of Patients</td>
</tr>
<tr>
<td>Occurs occasionally and can last up to 7 days</td>
<td>Lasts beyond 7 days and as long as 1 year</td>
<td>Lasts longer than 1 year without stopping</td>
</tr>
</tbody>
</table>

Patient Selection:

- Intolerant to at least one class I/III antiarrhythmic drug
- Left Atrium size up to 6 cm
- Patients in symptomatic AF for more than 12 months
- No limits on the duration of AF

1FU for EPI-Sense® Guided Coagulation System Data: PMA # P2000002
Patient Selection: Advanced AF Symptoms

Symptoms of Advanced AF Can Be Different²,³

Long-Standing Persistent AF Symptoms:

- Shortness of breath
- Dizziness
- Weakness
- Fatigue
- Lowered blood pressure
- Pain or pressure in the chest
- Rapid or irregular heartbeat
Left Atrial Appendage (LAA) and Afib

In non-valvular Afib, >90% of stroke causing clots from the left atrium originate in the LAA.\(^1\)
State of Concomitant Atrial Fibrillation Surgery
State of Surgical Ablation for Afib

- Surgical ablation has undergone many iterations since the success of the original 1987 Cox MAZE “Cut and Sew” technique.
- Radiofrequency and cryoablation are the two ablative technologies that have prevailed to mimic the lines created by the “Cut and Sew” technique.
- The following lesion sets are routinely used, and sometimes all of them are referred to as MAZE, though they have differing success rates:
  - Pulmonary Vein Isolation (PVI)
  - Box Lesion Set (BOX)
  - Left Atrial Lesion Set (LAL)
  - Bi-Atrial Lesion Set (MAZE)
Treatment of Concomitant Afib in USA

- **No AF**
- **AF Untreated**
- **AF Treated**

**MVR**
- 69% AF Treated
- 4,800
- 10,800
- 26,000 MVR/Y

**AVR**
- 24% AF Treated
- 13,600
- 4,400
- 50,000 AVR/Y

**CABG @ 6% Pre-Op AF**
- 33% AF Treated
- 6,422
- 3,178
- 160,000 Iso CABG/Y

**CABG @ 21% Pre-Op AF**
- 160,000 Iso CABG/Y
- 126,400
- 30,422

**13% Treated**

*Measured by admission for cardioversion for AF w/in 3Y prior to CABG*

---


**Bracht-Forbes Health Research, Private Reporter for McCue, Data Source: 2014 CMS SAF, August 2015.


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Why are patients undertreated?

- Lack of screening protocols within a complex referral pathway
- Concerns about adding risk to the primary procedure
  - Prolonged pump and cross-clamp time
  - Longer anesthesia
  - Added complications
- Not sure Afib treatment really offers advantages to patient
- Perceived lack of consensus on whether or not to treat Afib
- Lack of training and education in medical training
Atrial Fibrillation
Pathways and Goal of
MAZE Procedure
Mechanisms of Paroxysmal Afib (PAF)

The pulmonary veins are common Afib triggers in paroxysmal patients.
Ablation Treatment of PAF

Isolation of the pulmonary veins performed
PAF $\rightarrow$ Non-Paroxysmal Afib (nPAF)

The posterior left atrium becomes a common Afib trigger as patients move from paroxysmal to non-paroxysmal Afib.
Ablation Treatment PAF $\rightarrow$ nPAF

Isolation of the pulmonary veins and posterior left atrium performed.
Mechanisms of nPAF Afib

Maco-reentrant circuits are common Afib triggers in non-paroxysmal patients
MAZE IV Ablation Treatment of nPAF

MAZE IV lesion set performed with radiofrequency and cryoablation technologies
MAZE IV Ablation Treatment of nPAF

MAZE IV lesion set blocks all macro-re-entrant Afib triggers
Surgical Options for Treating Atrial Fibrillation
## Lesion Set Options

### Reported Experiences:

1 - 5 year retro and prospective peer-reviewed publications both on and off AADs

### Approach | Reported Experiences w/ Surgical Ablation | Ablation Duration | PVI Catheter Outcomes w/ Lone Afib
---|---|---|---
1. Pulmonary Vein Isolation (PVI) | PAF
~50-90%\(^5,13,14\) | + | PAF
~47 - 80%
47% - 1 ablation\(^1\)
74% - 2 ablations\(^1\)
80% - 3 ablations\(^1\)
~70% - meta-analysis\(^2\)

nPAF
~60%\(^6,13\) |  | nPAF
~25% - 52%
25% - 1 ablation\(^4\)
43% - multiple ablations\(^3\)
52% - multiple ablations\(^4\)
~50% - meta-analysis\(^2\)

2. Box Set Lesion (Box) | nPAF
~55-70%\(^7,15\) | ++ |  

3. Left Atrial Lesion Set (LAL) | nPAF
~73-86%\(^8,17\)
~20% fewer atrial flutter\(^9\) | +++ |  

4. Bi-Atrial Lesion Set (MAZE) | nPAF
~80-90%\(^10,11,12,16\) | ++++ |  

---

The success of various procedures may be influenced by several factors, which may predict the outcome. Duration of pre-procedural Afib, type of Afib, lesion set performed, left atrial size, patient’s age, atrial fibrillation wave <1.0mm, experience of the operator, left atrial reduction, and device used.

---

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Clinical Outcomes of Concomitant Surgical Ablation
Safety / Risk

The Society of Thoracic Surgeons 2017 Clinical Practice Guidelines for the Surgical Treatment of Atrial Fibrillation

Vinay Badhwar, MD, J. Scott Rankin, MD, Ralph J. Damiano, Jr, MD, A. Marc Gillinov, MD, Faisal G. Bakaeeen, MD, James R. Edgerton, MD, Jonathan M. Philpott, MD, Patrick M. McCarthy, MD, Steven F. Bolling, MD, Harold G. Roberts, MD, Vinod H. Thurani, MD, Rakesh M. Suri, MD, DPhil, Richard J. Shemin, MD, Scott Firestone, MS, Niv Ad, MD

Class I Recommendation:
“Surgical ablation for AF can be performed without additional risk of operative mortality or major morbidity…”
“The addition of the Cox Maze IV procedure did not significantly affect the procedural mortality.”
“Most patients are administered perioperative class I or III antiarrhythmic drugs, such as amiodarone, and these are often continued for 2 to 3 months after SA. The vast majority of patients who achieve stable sinus rhythm eventually can discontinue all antiarrhythmic agents ....”

1. Vinay Badhwar, J. Scott Rankin, Ralph J. Damiano, J, MD, A. Marc Gillinov, MD, Faisal G. Bakaeen, MD, James R. Edgerton, MD, Jonathan M. Philpott, MD, Patrick M. McCarthy, MD, Steven F. Bolling, MD, Harold G. Roberts, MD, Vinod H. Thusurani, MD, Rakesh M. Suri, MD, DPhil, Richard J. Shemin, MD, Scott Firestone, MS, Niv Ad, MD
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“After surgical ablation for AF, full anticoagulation therapy is common and reasonable until durable rhythm restoration is established, provided the patient otherwise meets criteria for the safe administration of systemic anticoagulant agents. Anticoagulation therapy is commonly continued until a stable sinus rhythm is documented by at least a 24-hour Holter monitor off all antiarrhythmic drugs, often between 2 and 6 months postoperatively. It is also common practice to obtain an echocardiogram before discontinuing anticoagulation to ensure adequate LA emptying by the absence of spontaneous LA echocardiography contrast.”
#1 Restoration of Normal Sinus Rhythm

37pts
Afib Treated
(nPAF)

66pts
Afib Not Treated
(nPAF)

P < 0.001
#2 Freedom from Long-Term Strokes

![Graph showing freedom from stroke over years after surgery for two groups: Group S (97.9%) and Group F (84.4%) with 345 and 102 patients respectively.](image)

- **Group S**: 345 patients, 97.9% freedom from stroke, 92.4% at 5 years, 89.4% at 10 years.
- **Group F**: 102 patients, 84.4% freedom from stroke, 76.6% at 5 years, 76.6% at 10 years.

**P-value**: 0.003

394pts Afib Treated (In Sinus Rhythm)

116pts Afib Treated (Not in Sinus Rhythm)

---


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#3 >40% Reduction in All-Cause Mortality

3,119pts
Afib Not Treated

626pts
Afib Treated

Figure 1. CABG vs. CABG + AF Ablation Mortality over 1 yr. Data represent % chance of death at each time interval (days)

Reference: Rankin, J. S., Forbes, M. J., Lerner, D., Ferguson, M., Badhwar, V. One-year Mortality and Costs after Surgical Ablation for Atrial Fibrillation Concomitant to Coronary Artery Bypass Grafting. Presented, EACTS Meeting, Oct. 2015, and in review, EJCTS.
#4 Increased Mid-Term Survival

565pts Afib Treated
248pts Afib Not Treated

Survival Probability

AF Ablated vs. AF Untreated, $p<.0001$
No AF vs. AF Untreated, $p<.0001$
AF Ablated vs. No AF, $p=.3096$


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#5 Increased Long-Term Survival

**108pts**  
Afib Treated  
(In Sinus Rhythm)

**136pts**  
Intractable or Afib  
Not Treated

---

**Fig 1. Actuarial survival curves for sinus and AF rhythm.** (AF = atrial afibrillation; — = sinus; · · · = AF.)


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#6 Decrease in All Cardiac Complications

108pts
Afib Treated
(In Sinus Rhythm)

136pts
Intractable or Afib
Not Treated

Fig 3. Actuarial freedom from all complications. (AF = atrial fibrillation; — = sinus; ··· = intractable AF; —— = untreated AF.)

P=0.002


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#7 An Improved Quality of Life

<table>
<thead>
<tr>
<th></th>
<th>Atrial Fibrillation Group (n = 51)</th>
<th>Sinus Rhythm Group (n = 40)</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>General health</td>
<td>49 ± 23</td>
<td>70 ± 19</td>
<td>&lt; 0.0001</td>
</tr>
<tr>
<td>Physical function</td>
<td>55 ± 26</td>
<td>76 ± 19</td>
<td>0.0001</td>
</tr>
<tr>
<td>Role physical</td>
<td>44 ± 41</td>
<td>54 ± 36</td>
<td>NS</td>
</tr>
<tr>
<td>Bodily pain</td>
<td>60 ± 30</td>
<td>71 ± 27</td>
<td>0.07</td>
</tr>
<tr>
<td>Mental health</td>
<td>52 ± 23</td>
<td>73 ± 29</td>
<td>0.0004</td>
</tr>
<tr>
<td>Role emotional</td>
<td>44 ± 41</td>
<td>60 ± 34</td>
<td>0.04</td>
</tr>
<tr>
<td>Vitalità</td>
<td>51 ± 24</td>
<td>67 ± 19</td>
<td>0.0007</td>
</tr>
<tr>
<td>Social function</td>
<td>66 ± 26</td>
<td>70 ± 23</td>
<td>NS</td>
</tr>
<tr>
<td>Total</td>
<td>95 ± 23</td>
<td>112 ± 16</td>
<td>0.0002</td>
</tr>
</tbody>
</table>

NS = not significant.
Societal Guidelines for Concomitant Atrial Fibrillation Surgery
Concomitant Class I Recommendation

Societies

References Available in Appendix C

Sensitivity: General Business Use. This document contains proprietary information and is intended for business use only.
Class I or II Recommendations
“It is advisable that all patients with documented Afib referred for other cardiac surgeries undergo a procedure for Afib...”

Heart Rhythm Society
American College of Cardiology
American Heart Association
Society of Thoracic Surgeons
European Heart Rhythm Association
European Cardiac Arrhythmia Society
European Society of Cardiothoracic Surgery
HRS, STS Align on Post-Ablation Follow Up

- There is a “blanking period” up to 3 months post ablation where the patient may still have some Afib until healed.
- Continuous ECG monitoring is recommended for patients post catheter ablation where anticoagulation may be discontinued (HRS).
- For surgical ablation patients, anticoagulation is continued between 2-6 months postop, with anticoagulation stopped after stable sinus rhythm is documented by 24-hr Holter monitor, and often an echocardiogram (STS).
- Monitoring at regular intervals by Cardiac Surgeon or EP, or both, helps to ensure appropriate postop management for optimized results.
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