Balloon Cryo-Ablation
For
Atrial Fibrillation

Aharon Medina, MD
Department of Cardiology
Shaare Zedek Medical Center,
Jerusalem, Israel
Disclosures

- Proctoring fee from Medtronic Israel
A.I. case study

- 68-year-old male patient.
- No structural heart disease.
- Paroxysmal AF since 2005.
- Presented with fatigue for a couple of months.
Atrial Flutter
What would you do?

- Change / add medication?
- Cardioversion?
- Rate control?
- Flutter ablation?
Follow up

- Patient underwent successful Isthmus Block on 16.01.2013 and returned to sinus rhythm during RF ablation.
- Was discharged on Amiodarone and Warfarin because of the history of AF.
- Two days later, he presented in the EW with palpitations and the following ECG:
Atrial Fibrillation
What would you do?

- Change / add medication?
- Cardioversion?
- Rate control?
- AF ablation?
The Strategies of Treatment of Atrial Fibrillation (STAF) study

J Am Coll Cardiol. 2003;41(10):1690-1696

- No differences between rhythm-control and rate-control strategies regarding primary endpoints.
### AFFIRM Study
**NEJM 2002, Circulation 2004**

<table>
<thead>
<tr>
<th></th>
<th>p-value</th>
<th>Risk Ratio 1</th>
<th>Risk Ratio 2</th>
<th>Risk Ratio 3</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age at enrollment</td>
<td>&lt;0.0001</td>
<td>1.06</td>
<td>1.04</td>
<td>1.08</td>
</tr>
<tr>
<td>Coronary artery disease</td>
<td>&lt;0.0001</td>
<td>1.65</td>
<td>1.31</td>
<td>2.07</td>
</tr>
<tr>
<td>Congestive heart failure</td>
<td>&lt;0.0001</td>
<td>1.83</td>
<td>1.45</td>
<td>2.32</td>
</tr>
<tr>
<td>Diabetes</td>
<td>&lt;0.0001</td>
<td>1.56</td>
<td>1.22</td>
<td>2.00</td>
</tr>
<tr>
<td>Stroke or TIA</td>
<td>&lt;0.0001</td>
<td>1.54</td>
<td>1.17</td>
<td>2.05</td>
</tr>
<tr>
<td>Smoking</td>
<td>&lt;0.0001</td>
<td>1.75</td>
<td>1.29</td>
<td>2.39</td>
</tr>
<tr>
<td>First episode of AFib</td>
<td>0.0067</td>
<td>1.27</td>
<td>1.01</td>
<td>1.58</td>
</tr>
<tr>
<td>Sinus rhythm</td>
<td>&lt;0.0001</td>
<td>0.54</td>
<td>0.42</td>
<td>0.70</td>
</tr>
<tr>
<td>Warfarin use</td>
<td>&lt;0.0001</td>
<td>0.47</td>
<td>0.36</td>
<td>0.61</td>
</tr>
<tr>
<td>Digoxin use</td>
<td>&lt;0.0001</td>
<td>1.50</td>
<td>1.18</td>
<td>1.89</td>
</tr>
<tr>
<td>Rhythm-control drug</td>
<td>0.0005</td>
<td>1.41</td>
<td>1.10</td>
<td>1.83</td>
</tr>
</tbody>
</table>
The presence of SR but not AAD use is associated with a lower risk of death.

These results indicate that if an effective method for maintaining SR with fewer adverse effects were available, it might improve survival.
Atrial Fibrillation Ablation

Ultimate Rhythm Control?
In some patients, especially young individuals with very symptomatic AF, ablation may be preferred over years of drug therapy.
Focal Atrial Fibrillation - Concept

- Single fast firing focus initiates chaotic activation of atria
- Proximal pulmonary veins focus location
- Elimination or isolation of pulmonary vein focus can cure Afib.
Microscopic Anatomy of Pulmonary Veins

Pulmonary Vein Isolation is Currently the Most Common Ablation Technique Used for Atrial Fibrillation

© 2009 Mayo Foundation for Medical Education and Research
Pulmonary Vein Isolation (PVI) is the Cornerstone of AF Ablation

“Ablation strategies which target the PVs and/or PV antrum are the cornerstone for most AF ablation procedures.”

Each vein should be isolated independently

Complete electrical isolation should be the goal for targeted PVs and entrance and/or exit block should be demonstrated
Anatomy of the Pulmonary Veins

- Nuclear magnetic resonance image of the ostia of the right and left superior and inferior PVs and the left atrial appendage

Principle of Radiofrequency catheter ablation

RF-current: 300-500 kHz
No muscle stimulation
30-60 s delivery
Heating of tissue at cath. tip
Coag. necrosis 8 x 4 x 4 mm
Challenges Using RF Focal Ablation Catheter to Isolate PV and Ablate Atrial Tissue

- Patient anatomy and atrial tissue depth is variable
- Cardiac contractions make maintaining position difficult
- Catheter force varies with position in heart
- Technically challenging
- Good lesions require transmurality
- Successful procedure requires contiguous lesions
Ablation Approach for Patients with Persistent Atrial Fibrillation

© 2009 Mayo Foundation for Medical Education and Research
Advantages of Cryo energy

- Minimal disruption of endothelium
  - Minimal thrombus production

- Maintenance of extracellular matrix - no collagen denaturation
  - No collagen shrinkage known to occur with thermal injury
  - Advantageous within venous structures - CS or PV’s
Balloon Cryoablation
Arctic Front® Catheter Design

- Pressurized N\textsubscript{2}O delivered through ultrafine injection tube
- Straightforward positioning: over-the-wire, steerable, good visibility
- Several safety mechanisms: double balloon, pressure and flow monitoring, blood detection
- Freezor® MAX operates on similar principles
Circumferential Lesion at LA-PV Junction

Lesion outline from Arctic Front Catheter 23 mm ablation in swine LA-PV junction (45-day survival). PV is cut open longitudinally and flattened out. Top of image: PV and its branches; Bottom: LA. TTC staining.

Towards the lungs

Towards the left atrium

Pulmonary vein tissue, transition between collagen and muscular sleeve

Muscular pulmonary veins sleeve distal to the lesion

Contiguous lesion performed by Arctic Front® Catheter
How the Arctic Front® Cardiac Cryo-Ablation System Works?

1. Liquid N₂O is delivered from the CryoConsole through an injection tube to the inner balloon.

2. Inside the balloon the liquid N₂O vaporizes and absorbs heat from the surrounding tissue.

3. The vapor is returned to the console through a lumen maintained under vacuum.

Arctic Front PV Isolation
Achieve™ Mapping Catheter

- Achieve is an intracardiac electrophysiology diagnostic catheter which can be deployed through the Arctic Front® guide wire lumen.

- Available in 15 mm and 20 mm loop diameters.

- Both diameters are compatible with 23 mm and 28 mm Arctic Front.
How Arctic Front® Balloon Catheter and Achieve™ Work?

1. Access targeted vein

2. Inflate and position

3. Occlude and ablate

4. Assess PVI
Pulmonary Vein Isolation
Potential Complications of AF Ablation

- Pulmonary vein stenosis → 5%
- Atrio-esophageal fistula → 0.5%
- Phrenic nerve palsy → 10%
Pulmonary Vein Stenosis
CT Analysis of the LA and Esophagus

Phrenic Nerve Palsy
Solutions?

- Ablate within the Left Atrium
  Not in the Pulmonary veins!
- Pace the Phrenic Nerve
- Monitor Esophageal Temperature
**Inclusion Criteria:**

- ≥ 2 documented AF Episodes in the prior 2 months
- Efficacy failure of ≥ 1 AAD (flecainide, propafenone, sotalol)

**STOP AF Trial**

**Sustained Treatment of Paroxysmal Atrial Fibrillation**

- N = 245
  - Randomized 2:1 to CRYO* or DRUG
  - 26 centers in US and Canada

- Cryoballoon ablation (CRYO) n = 163
- AAD Rx (DRUG) n = 82
- Redo ablation n = 31 (19%)
- Blanking period (90 day)
- AAD optimization
- Drug Crossover n = 65 (79%)

**Follow-up at 1, 3, 6, 9 & 12 Months**

* CRYO: Arctic Front® System
STOP AF Trial - Results

Cryo 69.9% (114/163)

Drugs 7.3% (6/82)

$p < 0.001$
AF Symptoms at 12M: CRYO Subjects

Baseline | 6 Months | 12 Months
---|---|---
AF Episodes (self reported) | 100% | 86% | 76%
Palpitations | 20% | 25% | 14%
Fatigue | 13% | 18% | 16%
Rapid heart beat | 20% | 25% | 25%
Dyspnea | 7% | 9% | 11%
Dizziness | 4% | 9% | 7%
Syncope | 1% | 1% | 4%

% Subjects
US Continued Access Protocol (CAP)

- Single-arm, non-randomized study (followed STOP AF)
  - 80 subjects in 12 centers
  - Follow-up at 1,3,6,12 months and 2,3,4,5 years post-cryoablation procedure

- Purpose to continue evaluating
  - Safety and efficacy of Arctic Front® system
  - The impact of experience on the learning curve

- The chronic success rate of Cryoballoon ablation increased with experience
CAP AF Safety Summary

- Phrenic nerve injury risk decreased from 11.2% in STOP AF to 4.8% in CAP AF
- Pulmonary vein stenosis decreased from 3.1% to 1.3%
- One patient had a second ablation procedure using RF. At this time, the root cause of the PV stenosis is under review.
• PV isolation was achieved without touch-up in 91.1% of patients, using the smaller balloon in 26.7%, the larger balloon in 25.6%, and both balloons in 47.7% of patients.

• Long-term follow-up data 12< months (median 30 months; interquartile range 18 to 48 months) were available for 451 patients.

• 278 patients (61.6%) were free of AF recurrence with no need for repeat procedures after the 3-month blanking period. Rates of freedom from AF after 1, 2, and 3 repeat procedures were 74.9%, 76.2%, and 76.9%, respectively.

• Use of the smaller balloons or both balloons produced the highest rates of long-term freedom from AF. Phrenic nerve palsy occurred in 12 patients (2%), resolving within 3 to 9 months.
Long Term Follow up – Vogt at al

JACC 2012
In a prospective European single-center study, 163 patients underwent PVI with a cryo-balloon. Five years success rate after a single ablation procedure was 53%.

Up to 11% of the patient experienced phrenic nerve palsy, all reversible within 9 months.
Back to our patient...

- He underwent successful Isolation of 4 PV’s on 13.03.2013
Cardiac CT and Trans-Esophageal Echocardiography were performed the day before the procedure.

Cardiac CT images underwent segmentation using the Ensite Velocity system (St. Jude Medical) to obtain a 3-D picture of the LA and assess the PVs diameters.

A single trans-septal puncture was performed and a deflectable sheath (FlexCath, Medtronic) was advanced into the LA.

A 28 mm only Cryo-balloon (Arctic Front, Medtronic) was advanced over a 20 mm lasso catheter (Achieve, Medtronic) placed through its central lumen.

Rt. phrenic nerve stimulation was performed during ablation of the right PVs.

The esophageal temperature was monitored during ablation.
CT Image of Pulmonary Veins
Cryo-Ablation of LSPV
Cryo-Ablation of LIPV
Cryo-Ablation of RIPV
Cryo-Ablation of RSPV
Cryo-Ablation of RIPV – Big Loop
Pulmonary Vein Isolation
Between July 2012 & May 2013, cryo-ablation was performed in 18 patients (age 56 [22-68]) for whom at least one AAD has failed: 12 with paroxysmal AF, 5 with persistent AF and 1 with left atrial tachycardia.

66 of 70 PV’s (94.3%) were successfully isolated. The right inferior PV was not isolated in 4 patients: 1 -not attempted, 1 - technical issue, 2 - unsuccessful.

Radiation time was 70 ± 32 min (dropping with learning curve).

After the 3 months blanking period, sinus rhythm was maintained in 80% of patients, follow up averaging 193 days (range 72-325).
Complications:

- Phrenic nerve palsy occurred in 1 patient (5.6%) and lasted for 30 minutes.
- Two patients had a minor pericardial effusion.
- No PV stenosis or esophageal fistula.
Cryoablation with the Arctic Front System:

• Effectively treats drug refractory PAF or early persistent AF.
• Is a safe and efficient procedure.
• Has shorter procedure times compared to RF ablation according to large published trials.
• Further follow up is needed to assess the long-term success rate.
So far in Sinus Rhythm... (3 months and 4 days)