Left Atrial Appendage Isolation

ACC– Indiana Annual Symposium
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The majority of LA clot seen in patients with AF is localized to the appendage (up to 90%) 
Coumadin therapy is associated with >50% reduction in CVA among patients with Afib 
Observational data from surgical Cox–MAZE procedures originally published in 1991: risk of stroke is low after surgical ligation 
Randomized data from PROTECT–AF suggesting WATCHMAN device non-inferiority to warfarin with significantly less hemorrhagic stroke 
No randomized data for any other approved device or surgical technique
Current LAA recommendations

- Cardiac surgery guidelines recommend LAA ligation in patients at high risk for stroke and/or Afib
- ACC/AHA/HRS guidelines allow for consideration of LAA ligation at the time of cardiac surgery (IIb, LOE C)
- 2014 ACC/AHA/HRS Afib guideline update makes no formal recommendation for device-based therapies
Data from PROTECT–AF and suggested non–inferiority to warfarin for prevention of CVA
Randomized PREVAIL trial showed improved safety but did not meet non–inferiority endpoint due to low risk in the warfarin group
Ongoing implants in the Continued Access Registry suggest improving safety with experience
Final FDA approval pending
## PROTECT–AF Results

<table>
<thead>
<tr>
<th></th>
<th>Watchman (n= 463)</th>
<th>Warfarin (n=244)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ischemic Stroke</td>
<td>3.0</td>
<td>4.9</td>
</tr>
<tr>
<td>CV/Unexplained death</td>
<td>0.7</td>
<td>2.7</td>
</tr>
<tr>
<td>Hemorrhagic Stroke</td>
<td>0.1</td>
<td>1.6</td>
</tr>
<tr>
<td>Mortality</td>
<td>3.0</td>
<td>4.8</td>
</tr>
<tr>
<td>Primary Safety Endpoint</td>
<td><strong>7.4</strong></td>
<td><strong>4.4</strong></td>
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Amplatzer Cardiac Plug (ACP)

- Transeptal delivery over a large sheath with direct insertion into the LAA
- Flexible, braided nitinol mesh delivered transeptal with 9–13F sheath
- Long term risk of device erosion and short term risk of perforation not well defined
- Clinical trials underway
**Coherex WaveCrest Occluder**

- Transeptal delivery over a large sheath with direct insertion into the LAA
- CE Mark Approval
- Clinical trials underway
- More gripping barbs than other devices, possibly better visualization
LARIAT
tm
suture delivery device

40mm pre-tied, “0” polyester suture loop mounted on collapsible snare

Magnetic wire system requires trans-septal and pericardial access
LARIAT system for LAA closure

- FDA approved for “soft tissue closure”
- Not proven for stroke prevention in randomized clinical studies
- Over 1000 implants in the USA and more in Europe
- Reimbursement by Medicare and private insurance usually on appeal only
- Currently utilized only in patients with no other option for stroke prevention
Pericardial Access
Transeptal access – 8.5F SL1
Magnetic rail
Device Delivery
Closure and Device Removal
Post-procedure

- 24–48 hours in hospital
- Pericardial drain overnight following procedure
- Colchicine prophylaxis for pericarditis
- 30 day TEE to confirm closure and evaluate for thrombus
LARIAT exclusions

- LAA width >40 mm
- Previous cardiac surgery or pericarditis
- Position of LAA behind the pulmonary artery
- Thrombus on TEE
- Previous ASD closure with implant
# Efficacy

<table>
<thead>
<tr>
<th></th>
<th>PLACE PLACE II Study</th>
<th>ACP Registry Data</th>
<th>WATCHMAN PROTECT AF Trial II</th>
</tr>
</thead>
<tbody>
<tr>
<td># Pts</td>
<td>89</td>
<td>183</td>
<td>463</td>
</tr>
<tr>
<td>Intent-to-Treat</td>
<td>85/89 (96%)</td>
<td>175/183 (96%)</td>
<td>408/463 (88%)</td>
</tr>
<tr>
<td>Acute Closure</td>
<td>81/85 (95%)</td>
<td>99.5</td>
<td>NA</td>
</tr>
<tr>
<td>30d Closure</td>
<td>81/85** (95%)</td>
<td>NA</td>
<td>NA</td>
</tr>
<tr>
<td>90d Closure</td>
<td>77/81** (95%)</td>
<td>NA</td>
<td>346/408 (85%)</td>
</tr>
<tr>
<td>6mos or 1 Year Closure</td>
<td>64/65** (98%)</td>
<td>98.9%</td>
<td>275/389** (71%)</td>
</tr>
<tr>
<td>Access Requirement</td>
<td>8.5F</td>
<td>9F-13F</td>
<td>14F</td>
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Lariat Initial US experience
Percutaneous Left Atrial Appendage Suture Ligation

Not Ready for Prime Time

Nikolaos Dagres, MD,† Sascha Rolf, MD,† Gerhard Hindricks, MD†
Effectiveness of LAA isolation vs. anticoagulation

- Randomized trials are lacking
- Patients included in studies already completed have generally been a low-risk, selected population
- “All-comers” registry data will provide important information regarding long term stroke risk and procedural complications
Antiplatelet/AC use after LAA closure

- For patients receiving suture-based closure with LARIAT procedure, common practice is ASA/Plavix for 30 days and then ASA alone.
- Some patients have been treated with ASA alone or no antiplatelet agents at all, safety outcomes in this group are unknown.
- Patients treated with implantable devices generally require DAPT or anticoagulation for at least 3 months but optimal strategy is not defined.
Who is the best candidate?
Is there an economic argument for LAA occlusion?
Future applications of LAA devices

- Stroke reduction for patients unable to tolerate anticoagulation
- Potential treatment in combination with improved ablation techniques for a truly “curative” afib procedure
- Alternative to anticoagulation in patients with high bleeding risk and/or desire to discontinue anticoagulation