NCDR Left Atrial Appendage Occlusion (LAAO) Registry: Review Of The First 3 Years

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• Research funding/ Salary support
  – NHLBI/NIH
  – American College of Cardiology (ACC)

• Advisory board/ Consulting- modest
  – Medtronic
  – Boston Scientific
  – Janssen Pharmaceuticals
  – Biosense Webster
NCDR LAAO Registry

• WATCHMAN approved in March 2015
• LAAO Registry developed through a collaboration
  – ACC, SCAI, FDA, CMS, Boston Scientific
• LAAO Registry launched late December 2015
• Enrollment began in January 2016
• Mandated for CMS reimbursement
• Supports post-market FDA surveillance study
LAAO Registry

• Hospitals are encouraged to submit data on all WATCHMAN
  – ~90% of hospitals do
  – Includes Lariat procedures; can support additional devices

• Data elements
  – 220 for index hospitalization
  – 60 per follow-up visit
  – 15 to support adverse event (AE) adjudication

• Adjudication performed using electronic algorithm and clinical events committee for some events

• Active follow-up for AEs and medical therapy though 2 years

• CMS claims for collection of AEs in years 3-4
Cumulative Procedures

12/2018 = 38,158

Freeman, JACC, 2020.
## Patient Characteristics

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>LAAO Registry 2016-2018 (N=38,158)</th>
<th>PROTECT AF trial 2005-2008 (N=463 implants)</th>
<th>PREVAIL trial 2011-2013 (N=269 implants)</th>
<th>EWOLUTION Registry 2013-2015 (N=1025)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Demographics</strong></td>
<td></td>
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</tr>
<tr>
<td>Age, mean (SD), year</td>
<td>76.0 (8.1)</td>
<td>71.7 (8.8)</td>
<td>74.0 (7.4)</td>
<td>73.4 (8.9)</td>
</tr>
<tr>
<td>Women, N (%)</td>
<td>15,672 (41.1)</td>
<td>137 (29.6)</td>
<td>87 (32.3)</td>
<td>411 (40.1)</td>
</tr>
<tr>
<td>Race, N (%)</td>
<td></td>
<td></td>
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</tr>
<tr>
<td>White/European</td>
<td>35,345 (92.6)</td>
<td>425 (91.8)</td>
<td>253 (94.1)</td>
<td>NA</td>
</tr>
<tr>
<td>Black/African American</td>
<td>1768 (4.6)</td>
<td>6 (1.3)</td>
<td>6 (2.2)</td>
<td>NA</td>
</tr>
<tr>
<td>Asian/Pacific Islander</td>
<td>670 (1.8)</td>
<td>5 (1.1)</td>
<td>1 (0.4)</td>
<td>NA</td>
</tr>
<tr>
<td>Hispanic ethnicity, N (%)</td>
<td>138 (0.4)</td>
<td>25 (5.4)</td>
<td>6 (2.2)</td>
<td>NA</td>
</tr>
<tr>
<td><strong>Medical History</strong></td>
<td></td>
<td></td>
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<td></td>
</tr>
<tr>
<td>Prior ischemic stroke/TIA, N (%)</td>
<td>10,425 (29.8)</td>
<td>82 (17.7)</td>
<td>74 (27.5)</td>
<td>312 (30.5)</td>
</tr>
<tr>
<td>Prior congestive heart failure, N (%)</td>
<td>14,266 (37.4)</td>
<td>124 (26.8)</td>
<td>63 (23.4)</td>
<td>350 (34.2)</td>
</tr>
<tr>
<td>Prior diabetes mellitus, N (%)</td>
<td>14,396 (37.7)</td>
<td>113 (24.4)</td>
<td>91 (33.8)</td>
<td>304 (29.7)</td>
</tr>
<tr>
<td>Prior hypertension, N (%)</td>
<td>35,148 (92.1)</td>
<td>413 (89.2)</td>
<td>238 (88.5)</td>
<td>885 (86.4)</td>
</tr>
<tr>
<td>Prior intracranial bleeding, N (%)</td>
<td>4550 (11.9)</td>
<td>NA</td>
<td>NA</td>
<td>155 (15.1)</td>
</tr>
<tr>
<td>Prior clinical bleeding, N (%)</td>
<td>26,466 (69.4)</td>
<td>NA</td>
<td>NA</td>
<td>396 (38.7)</td>
</tr>
</tbody>
</table>
LAAO Registry: CHA$_2$DS$_2$-VASc Scores

Mean CHA$_2$DS$_2$-VASc Scores
- LAAO = 4.6 (SD 1.5)
- PROTECT AF = 3.4 (SD 1.5)
- PREVAIL = 3.8 (SD 1.2)
- EWOLUTION = 4.5 (SD 1.6)
HAS BLED Score Distribution

Mean HAS BLED Scores
- LAAO = 3 (SD 1.1)
- EWOLUTION = 2.3 (1.2)
Annual Hospital Volume

Number of Hospitals

Median 30 (IQR 18-44)

Annual Case Volume

0
10
20
30
40
50
60
70
80
90
100
110
120

<10
10 to 19
20 to 29
30 to 39
40 to 49
50 to 59
60 to 69
70 to 79
>=80

NCDR®
NATIONAL CARDIOVASCULAR DATA REGISTRY
Annual Physician Volume

Median 12 (IQR 8-20)
Cancelled and Aborted Procedures

• Device deployed in 93% of procedures attempted
  – 3% cancelled prior to venous access
  – 4% aborted after access but before deploying device

• Approximately 50% of cancelled procedures due to LAA thrombus detected on day of procedure

• Rates of major AEs significantly higher among those who had cancelled or aborted procedures
Procedural Success

<table>
<thead>
<tr>
<th>Device</th>
<th>Percent of Procedures</th>
</tr>
</thead>
<tbody>
<tr>
<td>PROTECT-AF</td>
<td>90.9%</td>
</tr>
<tr>
<td>CAP</td>
<td>94.4%</td>
</tr>
<tr>
<td>PREVAIL</td>
<td>95.1%</td>
</tr>
<tr>
<td>CAP2</td>
<td>94.8%</td>
</tr>
<tr>
<td>EWOLUTION</td>
<td>98.5%</td>
</tr>
<tr>
<td>LAAO *</td>
<td>98.3%</td>
</tr>
</tbody>
</table>

*Acute procedural success = rate of success among procedures in which a device was deployed.

Among those with an acutely successful procedure 70 (0.2%) had device margin residual leak ≥5mm
Major In-hospital AEs

- Any Major Complication: 2.16%
- Pericardial Effusion Requiring Intervention: 1.39%
- Major Bleeding: 1.25%
- Cardiac Arrest: 0.24%
- Death: 0.19%
- Stroke/TIA: 0.17%
- Major Vascular Complication: 0.15%
# Major In-hospital AEs

<table>
<thead>
<tr>
<th>Adverse Event Type</th>
<th>N</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Overall</td>
<td>38158</td>
<td>100.00</td>
</tr>
<tr>
<td><strong>Neurologic Events</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ischemic Stroke</td>
<td>45</td>
<td>0.12</td>
</tr>
<tr>
<td>Hemorrhagic Stroke</td>
<td>3</td>
<td>0.01</td>
</tr>
<tr>
<td>Undetermined stroke</td>
<td>2</td>
<td>0.01</td>
</tr>
<tr>
<td>TIA</td>
<td>16</td>
<td>0.04</td>
</tr>
<tr>
<td>Intracranial Hemorrhage</td>
<td>3</td>
<td>0.01</td>
</tr>
<tr>
<td>Systemic Arterial Embolism</td>
<td>1</td>
<td>&lt;0.01</td>
</tr>
<tr>
<td>Myocardial Infarction</td>
<td>14</td>
<td>0.04</td>
</tr>
<tr>
<td>Device Embolization</td>
<td>30</td>
<td>0.07</td>
</tr>
</tbody>
</table>
Adverse Events Compared with Prior Studies

• Major in-hospital AEs (2.16%) lower than those reported in the pivotal trials at 7 days
  – PROTECT AF
    • Pericardial effusion requiring surgery or pericardiocentesis 4%
    • Major bleeding 3.5%
    • Procedure-related stroke 1.1%
    • Device embolization 0.4%
  – PREVAIL
    • Pericardial effusion requiring surgery or pericardiocentesis 1.9%
    • Procedure-related stroke 0.7%
    • Device embolization 0.7%
Adverse Events Compared with Prior Studies

• EWOLUTION Registry
  – 7-day procedure related AEs 2.8%
  – 1-day procedure related adverse event rates
    • Pericardial effusion 0.5%
    • Major bleeding 0.7%
    • Device embolization 0.2%
Conclusions

• NCDR LAAO Registry the largest registry of percutaneous LAAO procedures

• Over 38,000 WATCHMAN procedures between 2016-2018

• Hospital and physician procedure volumes were generally low to moderate but vary substantially
Conclusions

• Patients were higher risk for stroke and bleeding than prior studies
  – Most with prior clinically relevant bleeding
• Despite this, procedural characteristics and safety compared favorably with the pivotal trials
• LAAO Registry demonstrates the value of national registries to evaluate technology as adopted in clinical practice
Thank you