Nonpharmacologic Approach to Stroke Prevention for AF
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Disclosure Information
Bradley P. Knight MD
Consultant, Speaker, Investigator, Fellowship Support
• Boston Scientific
• Medtronic
• St. Jude Medical
• Biotronik
• Biosense Webster
• SentreHeart
• Jansen
• Apama Medical

Equity, Ownership, Stock
• None
Patient

- 60 y/o man with permanent AF, hypertension, diabetes, and previous stroke.
- Suffers a large intracranial bleed on warfarin
- Recovers well neurologically and is ambulatory
- Has another TIA
- Neurologist reviews brain MRI and determines he has an absolute contraindication to OAC
- What is your next step?
  1. Reassurance
  2. Percutaneous LAA occlusion
  3. Percutaneous LAA ligation
  4. Surgical LAA occlusion/removal

Left Atrial Appendage

Lee, Sanders, Kalman. Lancet 2012
Watchman Device

• Percutaneous LAA Transcatheter Occlusion

Implantation of Watchman LAA Closure Device
CMS NCD February, 2016

1. Non-valvular AF
2. A CHADS$_2$ score $\geq 2$ or CHA$_2$DS$_2$-VASc score $\geq 3$.
3. Suitability for short-term warfarin but deemed unable to take long-term oral anticoagulation following the conclusion of shared decision making, as LAAC is only covered as a second line therapy to oral anticoagulants.
4. Performed by a cardiologist and/or EP who has performed $\geq 25$ total transeptal punctures, and continues to perform $\geq 25$ transeptal punctures, of which at least 12 are LAAC, over a two-year period.
5. The physician has received the training by the manufacturer.
6. The patient will be enrolled in a national registry that tracks annual outcomes for at least four years.
7. A formal shared decision-making interaction has occurred with an independent non-interventional physician using an evidence-based decision tool on OAC prior to LAAC. Additionally, the interaction will be documented in the medical record
Professional Society Requirements for LAAO

Registries

More than 2,400 hospitals and over 2,000 outpatient providers worldwide participate in one or more of the ACC’s ten registries, forming a comprehensive network of cardiovascular care providers committed to ensuring evidence-based cardiovascular care, improving patient outcomes and lowering health care costs.

The ACC’s NCDR offers the following registries:

- **Hospital registries** for the in-patient setting
  - ACTION Registry®-GWTG™
  - AFib Ablation Registry™ - *Coming soon*
  - CathPCI Registry®
  - ICD Registry™
  - IMPACT Registry®
  - LAAO Registry™ - *New*
  - PVI Registry™
  - STS/ACC TVT Registry™

- **Outpatient registries** for the ambulatory care setting
  - Diabetes Collaborative Registry®
  - PINNACLE Registry®

ENDOTHELIALIZATION OF THE OCCLUDER

48 hours  2 weeks

1 month  3 months
Is OAC Needed after Watchman? ASAP Registry Results in 150 Pts

Comparison to expected annual stroke/TIA risk.

The mean CHADS2 score = 2.8
Predicted ischemic stroke rate = 7.4%

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Use of LARIAT Suture Delivery Device for Left Atrial Appendage Closure: FDA Safety Communication

Date Issued: July 13, 2015

The FDA conducted a search of the Manufacturer and User Facility Device Experience (MAUDE) database for reports of adverse events with the use of the LARIAT Suture Delivery Device and its associated devices. We identified 45 adverse events through June 30, 2015 that occurred in patients undergoing LAA closure procedures with the LARIAT Suture Delivery Device and/or its associated devices. These reports describe a patient deceased, and other serious medical complications including laceration and/or perforation of the heart, complete LAA detachment from the heart, bleeding (hemorrhage), low blood pressure (hypotension), fluid collection around the heart (pericardial effusion), fluid collection around the heart that causes low blood pressure and decreased heart function leading to shock (cardiac tamponade), and fluid collection around the lung (pleural effusion). Of the 45 adverse events reported to the FDA, 34 (approximately 75%) resulted in the need to perform emergency heart surgery.

Summary of Problem and Scope:
Atrial fibrillation is a common heart rhythm problem in which the heart beat (pulse) is irregular because the upper chambers of the heart (right atrium and left atrium) do not contract normally. As a result, a blood clot

Early Safety and Efficacy of Percutaneous Left Atrial Appendage Suture Ligation
Results From the U.S. Transcatheter LAA Ligation Consortium

Matthew J. Price, MD,* Douglas G. Gibson, MD,* Steven J. Valdes, MD,‡ Jason C. Schaff, MD,* Luigi E. Biasi, MD, PhD, Andrea Natale, MD,‡ J. David Burkhardt, MD,§ Ashish Perkar, MD,∥ Timothy J. Byrne, DO,∥ Brett Gidley, MD,∥ Joseph R. Angone, MD,∥ Jeffrey Goldstein, MD,∥ Kriagh Mouzon, MD,∥ Tras Rosé, MD,∥ Bradley Knight, MD,∥ Albert C. Lin, MD,∥ Miguel Valdes-Rodriguez, MD,∥

<table>
<thead>
<tr>
<th>TABLE 2 Major Bleeding Events During Hospitalization in the Study Population (n = 154)*</th>
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<tbody>
<tr>
<td>Major bleed</td>
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<tr>
<td>Any transfusion with overt bleeding</td>
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<tr>
<td>Overt bleed, hemoglobin drop ≤5 g/dL</td>
</tr>
<tr>
<td>Overt bleed, hemoglobin drop ≥5 g/dL</td>
</tr>
<tr>
<td>Cardiac tamponade</td>
</tr>
<tr>
<td>Bleeding requiring surgical control</td>
</tr>
<tr>
<td>Bleeding requiring vasopressor agents</td>
</tr>
<tr>
<td>Fatal bleeding</td>
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</tbody>
</table>

Values are n (%). Bleeding Academic Research Consortium type 3A or greater.
*More than 1 bleeding event may have occurred in a single patient.
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Surgical Staple Removal of LAA
Atriclip: EXCLUDE Trial

Efficacy: Successful exclusion of LAA at CTA or TEE imaging at 3-month follow-up = 95%.
Safety: LAA injuries or bleeding = 0%

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- Treatment:
  - Surgery - Full cut and sew Maze/LAA removal
  - Pacemaker - for post-op PAF with sinus pauses
  - 2-month follow up - Doing well in SR
LAAO: Future Directions

- Procedural Safety/ Experience with TSP
- Reimbursement
- Comparison to NOACs
- Need for post-procedure OAC (ASAP2)
- Options for patients with LAA clot
- Need for alternative non-occlusive LAA clot prevention devices