LEFT ATRIAL APPENDAGE CLOSURE INSTEAD OF ANTICOAGULATION; INDICATIONS AND OUTCOMES

Sheetal Chandhok, MD
Disclosures

• Boston Scientific:
  – Speaker (Watchman)
  – Trainer (Watchman)

• SentreHeart
  – Primary Investigator aMAZE trial (Lariat)
History

- 81 yo WM with Chronic AF on Warfarin therapy.
- Comorbid factors are HTN, OSA, CAD, CHF with pEF, Parkinson’s Disease.
- Episode of syncope felt to be orthostatic from Parkinsons, fell down flight of stairs, immobile for a day, almost fatal. Small brain bleed.
- 2 other major falls secondary to Parkinson’s
- GI bleed 9/2015 secondary to multiple ulcers in duodenum requiring transfusions
- Maintaining Warfarin, Last INR 2.8, previously on Xarelto
Background

• Atrial Fibrillation (AF) is a major risk factor for embolic stroke. Patients with AF have 5 times the risk of stroke compared to patients without AF

• AF accounts for at least 15-20% of all CVA

• Stroke is more severe for patients with AF, as they have a 70% chance of death or permanent disability

• AF-associated ischemic strokes generally occlude large intracranial arteries depriving a more extensive region of the brain of blood flow

• Compared with non-AF patients, AF patients have poorer survival and more recurrences of stroke during the first year of follow-up

2. Tu HT et al, Cerebrovascular Disease. 2010;30(4):389-95
Anticoagulation

• Anticoagulation reduces risk of thromboembolism (TE) in patients with Atrial Fibrillation.

• Meta-analysis looking at 29 trials included 28,044 participants. Compared to control, warfarin and antiplatelet agents reduced stroke by 64% and 22%, respectively.

• Warfarin was substantially more efficacious than antiplatelet therapy (relative risk reduction 39%)

• Validated in multiple studies.
• Powerful tool to assign stroke risk and provide evidence to use, or not use anticoagulation.

What’s our patient’s CHADS-VASC?

- CHF
- HTN
- AGE (2)
- Vascular (Nonobstructive CAD)

  – Score = 5 (6.7% yearly risk of CVA)
What’s his risk of major bleeding?

HAS-BLED score

**Table 4**

<table>
<thead>
<tr>
<th>HAS-BLED Score</th>
<th>Patients With Particular Score in the Whole Cohort*</th>
<th>Major Bleeding Events†</th>
<th>Patients With Particular Score Among Those Taking Warfarin Only*</th>
<th>Major Bleeding Events†</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>1,757 (24.0)</td>
<td>21 (1.2)</td>
<td>746 (20.4)</td>
<td>7 (0.9)</td>
</tr>
<tr>
<td>1</td>
<td>2,717 (37.1)</td>
<td>75 (2.8)</td>
<td>1,283 (35.0)</td>
<td>44 (3.4)</td>
</tr>
<tr>
<td>2</td>
<td>1,752 (23.9)</td>
<td>63 (3.6)</td>
<td>950 (25.9)</td>
<td>39 (4.1)</td>
</tr>
<tr>
<td>3</td>
<td>834 (11.4)</td>
<td>50 (6.0)</td>
<td>483 (13.2)</td>
<td>28 (5.8)</td>
</tr>
<tr>
<td>4</td>
<td>241 (3.3)</td>
<td>23 (9.5)</td>
<td>180 (4.9)</td>
<td>16 (8.9)</td>
</tr>
<tr>
<td>5</td>
<td>27 (0.4)</td>
<td>2 (7.4)</td>
<td>22 (0.6)</td>
<td>2 (9.1)</td>
</tr>
<tr>
<td>6</td>
<td>1 (0.0)</td>
<td>0</td>
<td>1 (0.0)</td>
<td>0</td>
</tr>
</tbody>
</table>

Values are n (%). *Percentage of column total. †Percentage of row total.

HAS-BLED = Hypertension, Abnormal Renal/Liver Function, Stroke, Bleeding History or Predisposition, Labile INR, Elderly, Drugs/Alcohol Concomitantly. SPORTIF = Stroke Prevention Using an ORal Thrombin Inhibitor in Atrial Fibrillation.

- HTN
- Bleeding Hx
- Elderly

- Score = 3 (at least. Near fatal fall) Risk is at least 5.8% per year
Options?

1) Eliquis? Pradaxa?
2) No antiocoagulation?
3) Same Warfarin?
4) Dual antiplatelet?
Despite Increasing NOAC Adoption, Overall Rate of Anticoagulation in High Risk NVAF Patients has Not Improved

Anticoagulant Use in Patients with NVAF and CHADS$_2$ $\geq$ 2

Results from the NCDR PINNACLE Registry$^1$

More than 90% of cardio-embolic events originate from the Left Atrial Appendage (LAA) in non-rheumatic Atrial Fibrillation. 1,2

A review of 23 studies found that thrombi were present in 17% of patients with nonrheumatic AF, of which 91% were located in the LAA.

Why?

• The left atrial appendage (LAA) is particularly vulnerable to thrombus formation due to its complex anatomy and low blood flow during AF.
• The LAA is a blind pouch 2-4 cm long. It has a narrow neck with multiple lobes.
• The endocardial surface is irregular, trabeculated and full of crypts. (pectinate muscles)
• Size and Shape of the appendage have been shown to predict stroke.
  – Larger LAA ostia, Larger neck diameter and greater length have a higher risk of stroke
  – “Chicken wing” shape is 79% less likely to have a stroke
• Johnson et al. described the LAA as “our most lethal human attachment”

LAA Morphologies

Cactus

Chicken Wing

Cauliflower

Windsock

LAA Anatomy/Morphology

Wind Sock:
An anatomy in which one dominant lobe of sufficient length is the primary structure.

Chicken Wing:
An anatomy whose main feature is a sharp bend in the dominant lobe of the LAA at some distance from the perceived LAA ostium.

Broccoli:
An anatomy whose main feature is an LAA that has limited overall length with more complex internal characteristics.
Left Atrial Appendage
Why do we have one?

• A major endocrine organ
  – produces ANP (Atrial natriuretic Peptide)
  – It also helps mediate thirst (animal studies)
  – The ANP concentration is 40 times higher in the LAA walls than in the rest of the atrial free wall and in the ventricles.

• Acts as a reservoir/decompression chamber
  – when left atrial pressure is high, it can accommodate extra blood. It is more distensible than the left atrium.
  – Animal experiments have shown that eliminating access to the LAA results in an increase in the size and mean pressure in the left atrium.

Watchman

- The WATCHMAN device, first implanted in 2002
- Self-expanding, open-ended nitinol frame with fixation anchors and a polyethylene membrane
- Catheter-based trans-septal delivery system.
- Permeable membrane, Warfarin is required for at least 6 weeks to prevent thrombus formation prior to endothelialization of the device.
• Protect AF trial
  – 707 pts with AF, CHADS2 >=1, randomized to Left atrial appendage closure (Watchman) or Warfarin.

• After 1065 patient-years of follow up, the primary endpoint (stroke, systemic embolism, or cardiovascular or unexplained death) was less in the WATCHMAN group vs the warfarin group (3.0% versus 4.9% per 100 patient-years) and achieved the criteria for noninferiority.

• However, the primary safety endpoint (excessive bleeding or procedure-related complications) was significantly worse in the WATCHMAN group (7.4% versus 4.4% per 100 patient years).
PROTECT AF 4-Year Results in JAMA

### WATCHMAN™ Met Criteria for both Noninferiority and Superiority for the Primary Composite Endpoint Compared to Warfarin

#### Table 2. Intention-to-Treat Primary Efficacy and Safety Outcomes According to Treatment Group by Bayesian Model

<table>
<thead>
<tr>
<th>Event</th>
<th>Device Group (n = 463)</th>
<th>Warfarin Group (n = 244)</th>
<th>Device/Warfarin Rate Ratio (95% Credible Interval)</th>
<th>Posterior Probabilities, %</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Events/Patient-Years</td>
<td>Observed Rate&lt;sup&gt;a&lt;/sup&gt;</td>
<td>Events/Patient-Years</td>
<td>Observed Rate&lt;sup&gt;a&lt;/sup&gt;</td>
</tr>
<tr>
<td>Primary efficacy end point&lt;sup&gt;b&lt;/sup&gt;</td>
<td>39/1720.2</td>
<td>2.3 (1.7-3.2)</td>
<td>34/900.8</td>
<td>3.8 (2.5-4.9)</td>
</tr>
<tr>
<td>Stroke</td>
<td>26/1720.7</td>
<td>1.5 (1.0-2.2)</td>
<td>20/900.9</td>
<td>2.2 (1.3-3.1)</td>
</tr>
<tr>
<td>Ischemic</td>
<td>24/1720.8</td>
<td>1.4 (0.9-2.1)</td>
<td>10/904.2</td>
<td>1.1 (0.5-1.7)</td>
</tr>
<tr>
<td>Hemorrhagic</td>
<td>3/1774.2</td>
<td>0.2 (0.0-0.4)</td>
<td>10/916.2</td>
<td>1.1 (0.5-1.8)</td>
</tr>
<tr>
<td>Disabling&lt;sup&gt;c&lt;/sup&gt;</td>
<td>8/1771.3</td>
<td>0.5 (0.2-0.8)</td>
<td>11/912.7</td>
<td>1.2 (0.6-1.9)</td>
</tr>
<tr>
<td>Nondisabling&lt;sup&gt;c&lt;/sup&gt;</td>
<td>18/1723.7</td>
<td>1.0 (0.7-1.7)</td>
<td>9/907.7</td>
<td>1.0 (0.4-1.7)</td>
</tr>
<tr>
<td>Systemic embolization</td>
<td>3/1773.6</td>
<td>0.2 (0.0-0.4)</td>
<td>0/919.5</td>
<td>NA</td>
</tr>
<tr>
<td>Cardiovascular or unexplained death</td>
<td>17/1774.3</td>
<td>1.0 (0.6-1.5)</td>
<td>22/919.4</td>
<td>2.4 (1.4-3.4)</td>
</tr>
<tr>
<td>Primary safety end point&lt;sup&gt;d&lt;/sup&gt;</td>
<td>60/1666.2</td>
<td>3.6 (2.8-4.6)</td>
<td>27/878.2</td>
<td>3.1 (2.0-4.3)</td>
</tr>
</tbody>
</table>

Abbreviation: NA, not applicable.

<sup>a</sup> Events per 100 patient-years (95% credible interval).

<sup>b</sup> Primary efficacy defined as composite of stroke, systemic embolization, or cardiovascular/unexplained death.

<sup>c</sup> Disabling or fatal strokes were those with a Modified Rankin Score of 3-6 after the stroke. Nondisabling strokes were those with Modified Rankin Scores of 0-2 after the stroke.

<sup>d</sup> Safety defined as procedure-related events (pericardial effusion requiring intervention or prolonged hospitalization, procedure-related stroke, or device embolization) and major bleeding (intracranial or bleeding requiring transfusion).

Watchman

*Protection but Risky*

- Periprocedural complications included 22 pericardial effusions (4.8%), 4 air emboli (0.9%), and 3 device embolizations (0.6%).
- Warfarin group had a higher incidence of major bleeding (4.1% versus 3.5%) and hemorrhagic stroke (2.5% versus 0.2%).
- Overall implantation success was 91% and at six months, 92% of patients in the WATCHMAN group were able to discontinue warfarin after a TEE.
Comparison of Safety in Protect AF

<table>
<thead>
<tr>
<th>Event</th>
<th>Watchman Group (n = 463)</th>
<th>Warfarin Group (n = 244)</th>
<th>Posterior Probabilities</th>
</tr>
</thead>
<tbody>
<tr>
<td>Primary Safety Endpoint</td>
<td>60/1666.2 (3.6 (2.8, 4.6))</td>
<td>27/878.2 (3.1 (2.0, 4.3))</td>
<td>1.17 (0.78, 1.95)</td>
</tr>
</tbody>
</table>

Graph showing the number of patients with events over time withWatchman and Control groups.
Watchman — PREVAIL

• PREVAIL: Prospective Randomized Evaluation of the WATCHMAN LAA Closure Device In Patients with Atrial Fibrillation Versus Long Term Warfarin Therapy

• Prospective, randomized, multicenter study to provide additional information on the safety and efficacy of the WATCHMAN LAA Closure Technology

• Confirmatory study conducted to provide additional information on the implant procedure and complication rates associated with the device

First Primary Endpoint: Primary efficacy

Death, Stroke, Systemic embolism

Statistical noninferiority **not** achieved, lower than expected events in control group. 95% CI higher than 1.75

<table>
<thead>
<tr>
<th>Device</th>
<th>Control</th>
<th>18-Month Rate Ratio (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>18-Month Rate</td>
<td>18-Month Rate</td>
<td>18-Month Rate Ratio (95% CI)</td>
</tr>
<tr>
<td>0.064</td>
<td>0.063</td>
<td><strong>1.07</strong> (0.57, 1.88)</td>
</tr>
</tbody>
</table>
Second Primary Endpoint: Late ischemic efficacy

- Comparison of composite of stroke, systemic embolism, excluding the first 7 days after randomization.
- To aid in evaluating the mechanism by which placement of the device improves outcome. (Local treatment noninferior to systemic AC)

Proved to be Noninferior.

*Figure 3* Kaplan-Meier Curve: Freedom From Second Primary Endpoint Event (Intention-to-Treat)

Late-ischemic events (stroke or systemic embolism >7 days' post-randomization) for Watchman (solid line) versus warfarin (dotted line) in the intent-to-treat population demonstrated noninferiority for the rate difference endpoint.
5-Year Outcomes After Left Atrial Appendage Closure
From the PREVAIL and PROTECT AF Trials

CENTRAL ILLUSTRATION Stroke Prevention in Nonvalvular Atrial Fibrillation With LAA Closure

<table>
<thead>
<tr>
<th>Event</th>
<th>HR</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>All stroke or SE</td>
<td>0.82</td>
<td>0.3</td>
</tr>
<tr>
<td>Ischemic stroke or SE</td>
<td>0.96</td>
<td>0.9</td>
</tr>
<tr>
<td>Hemorrhagic stroke</td>
<td>1.7</td>
<td>0.08</td>
</tr>
<tr>
<td>Ischemic stroke or SE &gt; 7 days</td>
<td>0.2</td>
<td>0.0022</td>
</tr>
<tr>
<td>Disabling/Fatal Stroke (MRS change of ≥2)</td>
<td>0.41</td>
<td>0.03</td>
</tr>
<tr>
<td>Non-Disabling Stroke</td>
<td>1.79</td>
<td>0.1</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>

Favors WATCHMAN ← Favors Warfarin

Hazard Ratio (95% CI)
5 Year Combined Data

(Top) In a patient-level meta-analysis combining the randomized PROTECT AF and PREVAIL trial cohorts, patients receiving the Watchman device were compared with patients receiving chronic warfarin for major clinical endpoints. Disabling was defined as an increase in the Modified Rankin Score by at least 2 points. (Bottom) The ischemic stroke rates of nonvalvular atrial fibrillation patients are shown as a function of the baseline CHA2DS2-VASc score using 2 large population databases (11,12). The dotted line represents untreated patients, whereas the solid line represents OAC-treated patients, largely warfarin. On this graph, the ischemic stroke rates and 95% confidence intervals of the LAAC arms from various clinical trials are shown. Because the baseline CHA2DS2-VASc scores for CAP and WASP were identical, they are arbitrarily offset for clarity; CAP2 and EWOLUTION were similarly offset for clarity. This imputed placebo analysis demonstrates the consistent performance of LAA closure with the Watchman device in preventing ischemic stroke across the various clinical studies. CAP = Continued Access to PROTECT AF registry; CAP2 = Continued Access to PREVAIL; CHA2DS2-VASc = congestive heart failure, hypertension, 75 years of age and older, diabetes mellitus, previous stroke or transient ischemic attack, vascular disease, 65 to 74 years of age, female; CI = confidence interval; CV = cardiovascular; EWOLUTION = Registry on Watchman Outcomes in Real-Life Utilization; HR = hazard ratio; LAA = left atrial appendage; MRS = Modified Rankin Score; PY = patient years; SE = systemic embolism; WASP = Registry on Watchman Outcomes in Real-Life Utilization WASP Registry.
FDA Approval

• FDA approval March 13, 2015
  – The WATCHMAN should only be used in patients who:
    • have atrial fibrillation not related to heart valve disease.
    • are at increased risk for a stroke.
    • are recommended for blood thinning medicines.
    • are suitable for warfarin (a blood thinner also known as Coumadin).
    • have an appropriate reason to seek a non-drug alternative to warfarin.
Medicare Approval

• Approved Feb 8, 2016

• The patient must have:
  – A CHADS2 score ≥ 2 or CHA2DS2-VASc score ≥ 3
  – A formal shared decision making interaction with an independent non-interventional physician using an evidence-based decision tool on oral anticoagulation in patients with NVAF prior to LAAC.
  – A 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 anticoagulation
  – The procedure must be performed by an interventional cardiologist(s), electrophysiologist(s) or cardiovascular surgeon(s) that meet the adequate training criteria

• The patient is enrolled in, and the MDT and hospital must participate in a prospective, national, audited registry that: 1) consecutively enrolls LAAC patients and 2) tracks the clinical annual outcomes for each patient for a period of at least four years from the time of the LAAC:
WATCHMAN™ Device
Endothelialization

Canine Model – 30 Day

Canine Model – 45 Day

Human Pathology – 9 Months Post-implant
(Non-device related death)

Images on file at Boston Scientific Corporation.
Results in animal models may not necessarily be indicative of clinical outcomes.
Our patient
Delivery of Watchman
What do you think?
TEE post delivery
Reposition and Core Wire Removal
After Repositioning
6 Weeks post TEE
Follow up

• Warfarin discontinued after 6 weeks.
• Plavix was discontinued June 2016
• Asa 325 indefinitely
• So far (fingers crossed) no events.
Bryn Mawr Data

• 85 Implants to date (Aug 2015 first implants)
• 83/85 acutely successful, 2 aborted for Size and incomplete closure.
• 81/83 to date were able to stop Warfarin at 6 weeks, no major (greater than 5mm) residual leaks or thrombus.
• 2 patients with residual leaks > 5mm underwent amplatzer closure at 12 weeks.
Safety Data

• All 85 patients
  – No strokes, no deaths, no vascular compromise
  – 1 presumed air embolism. Transient ST elevations and wall motion abnormality which resolved within 2-3 mins
  – 1 groin bleed at home next day, came back in for 48 hours
  – 1 asymptomatic PE picked up on CT scan in ER for abdominal complaints (imaged lower lungs and saw it)
  – 1 patient with LAA perforation requiring open surgical closure in EP lab, did well, home 5 days later.
Efficacy and safety of left atrial appendage closure with WATCHMAN in patients with or without contraindication to oral anticoagulation: 1-Year follow-up outcome data of the EWOLUTION trial

Lucas V. Boersma, MD, PhD, FESC,* Hueseyin Ince, MD,† Stephan Kische, MD,‡ Evgeny Pokushalov, MD, PhD,§ Thomas Schmitz, MD,‖ Boris Schmidt, MD,‖ Tommaso Gori, MD,‡ Felix Meincke, MD,∗∗ Alexey Vladimir Protopopov, MD, PhD,†† Timothy Betts, MD,†‡ David Foley, MD, PhD, FRCP, FACA, FACC, FESC,∥ Horst Sievert, MD,¶ Patrizio Mazzone, MD,° Tom De Potter, MD,‖‖ Elisa Vireca, MS,‖*** Kenneth Stein, MD, FHRS,‖‖ Martin W. Bergmann, MD, PhD, FESC,‖‖‖ for the EWOLUTION Investigators

From the *St. Antonius Ziekenhuis Nieuwegein/AMC, Amsterdam, The Netherlands, †Vivantes Klinikum Urban, Berlin, Germany, ‡Vivantes Klinikum im Friedrichshain, Berlin, Germany, §State Research Institute of Circulation Pathology, Novosibirsk, Russia, ††Elisabeth Krankenhaus Essen, Essen, Germany, ∥Cardiologisches Centrum Bethanien, Frankfurt/Main, Germany, ∞Universitätsmedizin Mainz and DZHK Standort Rhein-Main, Mainz, Germany, ∥∥Asklepios Klinik St. Georg, Cardiology, Hamburg, Germany, ′Cardiovascular Center of Regional State Hospital, Krasnoyarsk, Russia, ″Oxford University Hospitals NHS Trust, Oxford, United Kingdom, ‵Beaumont Hospital, Dublin, Ireland, ‴CardioVascular Center Frankfurt, Frankfurt, Germany, ‵′Ospedale San Raffaele, Milan, Italy, ′′′Once Lieve Vrouw Ziekenhuis, Aalst, Belgium, ″″Boston Scientific, Diegem, Belgium, ′′′′Boston Scientific, St. Paul, Minnesota, and ′′′′′Cardiologicum, Hamburg, Germany.

BACKGROUND Left atrial appendage (LAA) occlusion with WATCHMAN has emerged as viable alternative to vitamin K antagonists in randomized controlled trials.

OBJECTIVE EWOLUTION was designed to provide data in routine practice from a prospective multicenter registry.

METHODS A total of 1005 patients scheduled for a WATCHMAN implant were prospectively and sequentially enrolled at 47 centers. Indication for LAA closure was based on European Society of Cardiology guidelines. Follow-up and transesophageal echocardiography (TEE) were performed per local practice.

RESULTS The baseline CHA2DS2-VASc score was 4.5 ± 1.6; the mean age was 73.4 ± 9 years; previous transient ischemic attack/ischemic stroke was present in 312 (30.5%), 155 (15.1%) had previous hemorrhagic stroke, and 320 (31.3%) had a history of major bleeding; and 750 (73%) were deemed unsuitable for oral anticoagulation therapy. WATCHMAN implant succeeded in 1005 (98.5%) of patients, without leaks >5 mm in 1002 (99.3%) with at least 1 TEE follow-up in 875 patients (87%). Antiplatelet therapy was used in 784 (83%), while vitamin K antagonists were used in only 75 (8%). At 1 year, mortality was 98 (9.3%), reflecting the advanced age and comorbidities in this population. Device thrombus was observed in 28 patients at routine TEE (3.7%) and was not correlated with the drug regimen (P = .14). Ischemic stroke rate was 1.1% (relative risk 84% vs estimated historical data); the major bleeding rate was 2.6% and was predominantly (2.3%) nonprocedure/device related.

CONCLUSION LAA closure with the WATCHMAN device has a high implant and sealing success. This method of stroke risk reduction appears to be safe and effective with an ischemic stroke rate as low as 1.1%, even though 73% of patients had a contraindication to and were not using oral anticoagulation.

KEYWORDS Stroke; Left atrial appendage; Atrial fibrillation; LAA closure; Bleeding

(Heart Rhythm 2017;14:1302–1308) © 2017 The Authors. Published by Elsevier Inc. on behalf of Heart Rhythm Society. This is an open access article under the CC BY-NC-ND license (http://creativecommons.org/licenses/by-nc-nd/4.0/).
POST-APPROVAL U.S. EXPERIENCE WITH LEFT ATRIAL APPENDAGE CLOSURE FOR STROKE PREVENTION IN ATRIAL FIBRILLATION

Vivek Y. Reddy, MD, 1 Douglas N. Gibson, MD, 1 Srinath Kar, MD, 1 William O’Neill, MD, 2 Shefali K. Echt, MD, 1 Rodney P. Horton, MD, 1 Maurice Buchbinder, MD, 1 Nicole T. Gordon, BSEE, 1 David R. Holmes, MD 1

ABSTRACT

BACKGROUND Left atrial appendage closure (LAAC) was approved by the U.S. Food and Drug Administration (FDA) as a stroke prevention alternative to warfarin for patients with nonvalvular atrial fibrillation. However, clinical decision-making is confounded by the fact that although LAAC attenuates the anticoagulant-related lifetime risk of bleeding, implantation is associated with upfront complications. Thus, enthusiasm for LAAC as a treatment option has been appropriately tempered, particularly as the therapy is introduced beyond the clinical trial sites into general clinical practice.

OBJECTIVES This study evaluated the acute procedural performance and complication rates for all cases performed in the United States since FDA approval.

METHODS In the absence of a formal national clinical registry since regulatory approval in March 2015, we obtained procedural data on implantation procedures. Every LAAC procedure requires the presence of a manufacturer clinical specialist and the procedural parameter and periprocedural complication data to be collected using a standardized process and forms.

RESULTS In 3,822 consecutive cases, implantation was successful in 3,653 (95.6%), with a median procedure time of 50 min (range 10 to 210 min). Implanting physicians performing these procedures (N = 382) included 71% new, nonclinical trial implanters, who performed 95% of the procedures. Procedure complication rates included 39 pericardial tamponades (0.39%) (24 treated percutaneously, 12 surgically, and 3 fatal), 3 procedure-related strokes (0.08%), 9 device embolizations (0.34%) (6 requiring surgical removal), and 3 procedure-related deaths (0.08%).

CONCLUSIONS Despite a large fraction of previously inexperienced operators, in the real-world post-FDA approval experience of LAAC, procedural success was high and complication rates were low. (J Am Coll Cardiol 2017;69:259-61) © 2017 The Authors. Published by Elsevier on behalf of the American College of Cardiology Foundation. This is an open access article under the CC BY-NC-ND license (http://creativecommons.org/licenses/by-nc-nd/4.0/).
Real World US Data since Market Release

**CENTRAL ILLUSTRATION:** Major Complication Rates Across Watchman Clinical Studies

<table>
<thead>
<tr>
<th>Procedural Parameters</th>
<th>Aggregate Clinical Data</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of Procedures</td>
<td>6,720</td>
</tr>
<tr>
<td>Implantation Success, %</td>
<td>94.9%</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Complication Rates</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Pericardial Tamponade</td>
<td>1.24%</td>
</tr>
<tr>
<td>Procedure-Related Stroke</td>
<td>0.18%</td>
</tr>
<tr>
<td>Device Embolization</td>
<td>0.25%</td>
</tr>
<tr>
<td>Procedure-Related Death</td>
<td>0.06%</td>
</tr>
</tbody>
</table>

Who is a candidate?

- **Bleeding Hx**
  - GI/Urinary/Brain, etc
- **Labile INR’s**
  - inability to maintain stable INR
  - inability to comply with regular INR monitoring and unavailability of an approved alternative OAC
- **Falls hx**
- **Medical condition, occupation, or lifestyle placing patient at high risk of major bleeding secondary to trauma**
- **Remember the guidelines are broad:**
  - “have an appropriate reason to seek a non-drug alternative to warfarin.” (FDA)
  - “A 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 anticoagulation.” (Medicare)
- **Assess each patient’s risk individually and weigh against risk of procedure**