Discussion of Peri-procedural Safety of Left Atrial Appendage Occlusion with the WATCHMAN Device: Preliminary Data From the EWOLUTION Registry

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Cutting Edge Technologies in Electrophysiology
American Heart Association Scientific Sessions
Orlando, FL November 9 2015
We Need to Know About the Safety of Therapies in Practice
What Do Trials Say about Complications of WATCHMAN?

**TABLE 7** Comparison of Outcomes in Device Patients in PROTECT AF, CAP, and PREVAIL

<table>
<thead>
<tr>
<th></th>
<th>PROTECT AF</th>
<th>CAP</th>
<th>PREVAIL</th>
<th>p Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Implant success</td>
<td>90.9</td>
<td>94.3</td>
<td>95.1</td>
<td>0.04</td>
</tr>
<tr>
<td>All 7-day procedural complications</td>
<td>8.7</td>
<td>4.2</td>
<td>4.5</td>
<td>0.004</td>
</tr>
<tr>
<td>Pericardial effusion requiring surgery</td>
<td>1.6</td>
<td>0.2</td>
<td>0.4</td>
<td>0.03</td>
</tr>
<tr>
<td>Pericardial effusion with pericardiocentesis</td>
<td>2.4</td>
<td>1.2</td>
<td>1.5</td>
<td>0.318</td>
</tr>
<tr>
<td>Procedure-related strokes</td>
<td>1.1</td>
<td>0.0</td>
<td>0.7</td>
<td>0.02</td>
</tr>
<tr>
<td>Device embolization</td>
<td>0.4</td>
<td>0.2</td>
<td>0.7</td>
<td>0.368</td>
</tr>
</tbody>
</table>

EWolution 98.5% 2.8%

Abbreviations as in Tables 3 and 6.

Holmes DR et al. J Am Coll Cardiol 2014;64:1–12
What Has EWOLUTION Found (So Far)?

- Patients in practice differ from trials
  - Higher stroke & bleeding risks
  - Many ineligible for anticoagulation
- Higher procedural success
  - Experience of operators
- Lower short-term outcomes
  - Ascertainment of endpoints
Key Challenges for Post-market Observational Registries

- Completeness of enrollment & endpoints
- No (or inadequate) comparison groups
- Longitudinal follow up
  - Clinical events
  - Other therapies
Other Efforts to Understand Outcomes of WATCHMAN in Practice

- **WATCHMAN New Enrollment Study**
  1,000 patients with follow up for 2 years (clinical); 5 years (claims)

- **WATCHMAN Novel Surveillance Study**
  1,000 patients with follow up for 1 year (clinical); 5 years (claims) in a registry

“Now this is not the end. It is not even the beginning of the end. But it is, perhaps, the end of the beginning.”

--Sir Winston Churchill