Incidence, Prevention, and Management of Periprocedural Complications of Left Atrial Appendage Occlusion

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KEYWORDS
- Left atrial appendage occlusion
- Device embolization
- Periprocedural complications
- Pericardial effusion

KEY POINTS
- Major procedural complications related to left atrial appendage occlusion (LAAO) are relatively infrequent in contemporary practice (<1%–2%) but may be associated with major morbidity and mortality.
- LAAO operators should be knowledgeable about these potential complications and management.
- Often, prompt recognition and treatment are necessary to avoid rapid deterioration and dire consequences.
- With stringent guidelines on operator training and competency requirements, and on procedural-technical refinements, LAAO can be performed safely with low complications rates.
- LAAO is a feasible, safe, and effective alternative to oral anticoagulation for nonvalvular atrial fibrillation stroke prevention.

INTRODUCTION
The left atrial appendage (LAA) is a multilobed, embryologic remnant of the left atrium (LA) that exhibits highly variable and complex anatomy unique to each patient. Thus, LAA occlusion (LAAO) requires careful evaluation and planning on a case-by-case basis. Currently, the percutaneous endovascular approach is most widely used for LAAO. This technique requires transseptal puncture (TSP), which increases the risk of the procedure. The thin wall of the LAA and

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manipulation of large-bore sheaths to achieve coaxial device delivery can increase the risk of perforation. The low flow-low pressure circulation of the LA also predisposes to thromboembolism and air embolism. Over the last decade, improved experience and meticulous technique has brought dramatic reduction in the incidence of major procedural complications (death, stroke, cardiac tamponade, device embolization). Currently, the Watchman (Boston Scientific, Natick, MA) and Amplatzer Cardiac Plug (ACP) or Amulet (Abbott Vascular Inc, Minneapolis, MN) are most commonly implanted worldwide; hence this article mainly focuses on these devices. Table 1 provides a summary of the major complications reported across leading trials of LAAO.

PERICARDIAL EFFUSION AND CARDIAC TAMPONADE

Incidence

Pericardial effusion is the most common complication after LAAO. The incidence of pericardial effusion has declined over time with improved operator skills. In the Percutaneous Closure of the Left Atrial Appendage Versus Warfarin Therapy for Prevention of Stroke in Patients with Atrial Fibrillation (PROTECT AF) trial, 2009, the first landmark LAA closure study using the Watchman device, pericardial effusion requiring intervention was reported in 4.3% of the study population. This has steadily declined since, with PREVAIL (Prospective Randomized Evaluation of the WATCHMAN LAA Closure Device in Patients with Atrial Fibrillation versus Long Term Warfarin Therapy), 2014, and the Continued Access Protocol Registry (CAP2) reporting a frequency of 1.9%. The overall incidence of cardiac tamponade is approximately 1.3% in a pooled analysis of Watchman clinical trials and registries. The frequency of pericardial effusion in early clinical trials with the ACP device ranged between 1.9% and 3.7%. In the most recently published Amulet Postmarketing Registry of 1088 patients, the incidence of cardiac tamponade was 1.2%.

Classification

The Munich LAA consensus document classified pericardial effusion based on timing of occurrence.

### Table 1

<table>
<thead>
<tr>
<th>Study</th>
<th>Study Features</th>
<th>Pericardial Tamponade (% or Surgical Treatment (%))</th>
<th>Stroke (%)</th>
<th>Device Embolism (%)</th>
<th>Mortality (%)</th>
<th>Vascular or Major Bleeding (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Holmes et al, 2009 PROTECT AF</td>
<td>Watchman RCT N = 707 I = 463</td>
<td>22 (4.8) or 7 (1.5)</td>
<td>5 (1.1)</td>
<td>3 (0.6)</td>
<td>0 (0)</td>
<td>1 (0.2) or 16 (3.5)²</td>
</tr>
<tr>
<td>Holmes et al, 2014 PREVAIL</td>
<td>Watchman RCT N = 407 I = 269</td>
<td>5 (1.9) or 1 (0.4)</td>
<td>1 (0.4)</td>
<td>2 (0.7)</td>
<td>0 (0)</td>
<td>1 (0.4) or 1 (0.4)³</td>
</tr>
<tr>
<td>Reddy et al, 2011 CAP</td>
<td>Watchman registry N = 460</td>
<td>8 (1.4) or 1 (0.2)</td>
<td>0 (0)</td>
<td>1 (0.2)</td>
<td>0 (0)</td>
<td>1 (0.2) or 3 (0.7)³</td>
</tr>
<tr>
<td>CAP2</td>
<td>Watchman registry N = 1019</td>
<td>2 (0.2) or NA</td>
<td>1 (0.1)</td>
<td>2 (0.2)</td>
<td>1 (0.1)</td>
<td>4 (0.4) or 7 (0.7)³</td>
</tr>
<tr>
<td>Tzikas et al, 2016 E沃LUTION</td>
<td>ACP retrospective analysis multicenter N = 1047</td>
<td>13 (1.24) or NA</td>
<td>9 (0.9)</td>
<td>8 (0.8)</td>
<td>8 (0.76)</td>
<td>4 (0.4) or 13 (1.24)³</td>
</tr>
</tbody>
</table>

Abbreviations: CAP, continued access protocol; I, intervention (device) group subjects; N, total enrolled subjects; NA, not available; RCT, randomized controlled trial.

² Arteriovenous fistula in 1 subject and major bleeding defined as greater than 2 units of packed red blood cells or surgical intervention in 16 subjects.
³ Arteriovenous fistula in 1 subject and major bleeding in 1 subject.
⁴ Pseudoaneurysm in 1 subject and bleeding in 3 subjects.
⁵ Vascular damage to the groin in 4 subjects and major bleeding per Bleeding Academic Research Consortium criteria.
⁶ Pseudoaneurysm in 3 subjects and arteriovenous fistula in 1 subject, 8 subjects had bleeding from femoral artery and its association with the LAA procedure was not clear, 1 subject had pulmonary artery perforation, and 2 subjects had gastrointestinal bleeding.