Anti-Thrombotic Regimen
for Post-LAAO Status

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When do we consider LAAO?

OAC intractable?

1) Cannot use (contraindication d/t bleeding)
2) Not enough (recurrent stroke despite OAC)
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Pison et al. Europace 2015
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Current guideline

LAA occlusion may be considered for stroke prevention in patients with AF and contra-indications for long-term anticoagulant treatment (e.g. those with a previous life-threatening bleed without a reversible cause).

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<tr>
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<th>IIb</th>
<th>B</th>
<th>449, 453, 454</th>
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ESC guideline 2016
Protocol in Watchman

- **PROTECT AF (Watchman)**
  - ~ 45 d: ASA + Warfarin
  - ~ 6 m: ASA + clopidogrel
  - lifelong: ASA

- **PREVAIL (Watchman), by 45 day TEE**

<table>
<thead>
<tr>
<th>LAA seal</th>
<th>No LAA seal</th>
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<tbody>
<tr>
<td>45 d ~ 6 m</td>
<td>ASA 325 + clopidogrel</td>
</tr>
<tr>
<td>6 m ~ 5 yr</td>
<td>ASA 325</td>
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In case of contraindications to OAC

- AF, CHADS-VASc 4.4, Contraindication for OAC
- N=150, Watchman, 6 m DAPT -> ASA (lifelong)
- Device associated thrombus: 4% for 6 m (to stroke:
  1.7%, 5.0% as expected). cf) 4.2% in PROTECT AF
  ASAP study. JACC 2013
- ASAP-TOO trial (ongoing RCT)
Lifelong aspirin after LAAO sealing?

- AF, unsuitable for warfarin, n=5599, ASA vs apixaban
- similar bleeding (1.2 vs 1.4%), less effective (HR 2.4)
  AVERROES trial. *NEJM* 2011

- Other LA device (PFO occluder): lifelong ASA is dispensable (1 m DAPT, 5 m ASA)
NOAC in patients with Watchman

• Retrospective registry, n=214, 6 w NOAC -> ASA
• Device-associated thrombus: 0.9% at 4 m (but on ASA)
  Enomoto et al. *Heart Rhythm* 2017

• Of the EWOLUTION registry, NOAC (n=113)
• Device-associated thrombus: 1.4% at 3 m
  Bergmann et al. *Presented at TCT* 2016
Watchman, ACP and Amulet
Device associated thrombus (1)

- Incidence: 0~8.2% (3.9%), 3.6% at 6 w

- Not equivalent to stroke
  - Mostly asymptomatic, stroke in 7.3%

Lempereur et al. *Cather and Card Interv* 2017
Device associated thrombus (2)

- Treatments: LMWH, iv heparin, OAC
  -> 2 w ~ 6m
  -> mostly complete resolution (95%)

  Lempereur et al. *Cather and Card Interv* 2017

- Lower rate of thrombus in DAPT ?
  -> 1/59 (1.7%) vs 3/29 (15.8%)

  KR Chun et al. *Heart Rhythm* 2017
Importance of patients factor

- PROTECT AF protocol (on aspirin)
- Thrombus 10 yr following implantation

Shamin et al. *Echocardiography* 2017
Importance of procedural factor

Sedaghat et al. JACC EP 2017
Potential risk factors for device associated thrombus

1) Patients factors
   - CHADS-VASc, bleeding tendency (platelet, PT)

2) Echocardiographic
   - low EF, SEC, hugh LA

3) Procedural:
   - deep implant, incomplete sealing

4) Device
   - screw, connector pin
Considerations for decision

• Is OAC absolutely contraindicated? If possible, continue OAC as adjunctive therapy.

• Some patients unsuitable for warfarin are suitable for NOAC.

• Regular image surveillance is important
Summary of data (1)

- no significant difference btw Watchman and ACP/Amulet so far

- Long term use of aspirin
  - No role of aspirin in AF
  - Dispensable in the ASD device
Summary of data (2)

- Regimen during initial period (6m)

<table>
<thead>
<tr>
<th>OAC favor</th>
<th>DAPT favor</th>
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<tbody>
<tr>
<td>thrombus is exclusively treated by OAC</td>
<td>1.7% (DAPT) vs 15.8% (small registry)</td>
</tr>
<tr>
<td>Thrombus peak after OAC in PROTECT AF</td>
<td>Similar results even with different protocol</td>
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<tr>
<td>Favorable data on NOAC</td>
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**Consensus for anti-thrombotic regimen**

- Heparin during procedure, loading warfarin and ASA
- 6m DAPT and lifelong aspirin

<table>
<thead>
<tr>
<th></th>
<th>Aspirin</th>
<th>Warfarin</th>
<th>Clopidogrel</th>
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<tbody>
<tr>
<td>Watchman</td>
<td>lifelong</td>
<td>45 d or till closure</td>
<td>after warfarin till 6 m</td>
</tr>
<tr>
<td>Watchman (unsuitable warfarin)</td>
<td>lifelong</td>
<td>none</td>
<td>6 m or till closure</td>
</tr>
<tr>
<td>ACP/Amulet</td>
<td>lifelong</td>
<td>none</td>
<td>6 m or till closure</td>
</tr>
</tbody>
</table>

*adequate closure: < 5mm leak*  

EHRA consensus. *Europace 2014*
Ongoing RCTs

- ASAP-TOO trial (unsuitable for OAC)
  - Watchman vs. control
- SWISS-APERO, Amulet IDE
  - Watchman vs. Amulet
- The role of NOAC in LAAO
- Duration of ASA after LAAO
  - 1m vs. 6m
- PRAGUE-17
  - NOAC vs. LAAO
The optimal antithrombotic regimen and its duration after Watchman implantation has yet to be determined. This treatment could be tailored according to the individual patient’s risk of DAT and bleeding, and antiplatelet agents could be used for patients with a high bleeding risk. In patients eligible for OAT, preliminary data have shown that NOACs may represent an interesting alternative to Warfarin after Watchman implantation. Larger clinical trials are needed to confirm the safety and efficacy of NOACs over warfarin in this setting.