



EWOLUTION: 3-months outcome of Left Atrial Appendage Closure with the WATCHMAN device in Europe

Discussion

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Potential conflicts of interest

Speaker's name: Farrel Hellig

I have the following potential conflicts of interest to report:

Proctor for Watchman, BOSTON SCIENTIFIC

Honoraria from BOSTON SCIENTIFIC

Why do we need LAA closure?

- To prevent stroke in patients with non-valvular AF
- As an alternative to anticoagulation
- In patients who have bled or with high bleeding risk

What do we need to show from trials?

- Low risk of stroke
- Implantation is safe
- Bleeding is reduced
- Durability long term

What have been the challenges thus far?

- Complications at implantation
- Uncertainty about the post procedure drug regimen

EWOLUTION: 3-months outcome

How does it further our knowledge
and what new questions are raised?

This was the correct patient population

- **Higher risk of stroke and bleeding than in prior trials**
- **72% had a contraindication to warfarin**
 - PROTECT and PREVAIL Trials mandated warfarin for 45 days
 - We most want LAA closure when warfarin is not an option

The procedure was predictable and safe

Implant success 98.5%

- PROTECT 88%, PREVAIL 91%, CAP 95%

Low rate of procedural complications (even if centers were new)

- Effusion/tamponade 0.7%, stroke 0.4%, embolisation 0.4%

Reflects successful device rollout and training

- **With experience the first device was the correct size in 98.8%**
- **Compression 17% (IFU 8-20%)**
 - Policy of upsizing results in complete seal or colour jet \leq 5mm in 99.7%

Bleeding?

- **Bleeding rate 4.1% at 3 months**
 - Patients mostly are on some antiplatelet or antithrombotic regimen
 - We need more time to evaluate bleeding

What is the ideal post implant drug regimen?

- It appears acceptable to omit warfarin
- **Thrombus on the device and Bleeding SAEs**
 - Difficult: patient characteristics likely dictate drug choices
 - There were numeric differences between regimens (non significant)
 - Rates were low for both thrombus and bleeding with NOACs

What would we like to know next?

- Could post procedure NOACs be the best option?
 - Dabigatran now has an antidote
- Can aspirin be omitted in the longer term?

Bleeding During Treatment With Aspirin vs Apixaban in Patients With Atrial Fibrillation Unsuitable for Warfarin (AVERROES)

Bleeding: no difference (5599 patients)

3.8%/year with Aspirin

4.5%/year with Apixaban

Flaker GC et al, *Stroke*. 2012;43:3291-3297

What trials should happen next?

- Is it too early to recommend **NOAC only** for a period post procedure?
 - Perhaps.. BUT this would be an important next trial
- For LAA closure to reach its full potential to reduce bleeding:
- The ideal would be to **omit aspirin**
 - A trial of **NOAC only** for a period post procedure with **no aspirin** to follow.....?

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