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Volume 65, Issue 10S Arrhythmias and Clinical EP**META-ANALYSIS OF RANDOMIZED CONTROL TRIALS (RCTS) COMPARING PERCUTANEOUS LEFT ATRIAL APPENDAGE (WATCHMAN DEVICE) CLOSURE VERSUS ADJUSTED DOSE WARFARIN FOR STROKE PROPHYLAXIS IN NON-VALVULAR ATRIAL FIBRILLATION**

Poster Contributions

Poster Hall B1

Saturday, March 14, 2015, 3:45 p.m.-4:30 p.m.

Session Title: New Device Indications and Therapies

Abstract Category: 6. Arrhythmias and Clinical EP: Devices

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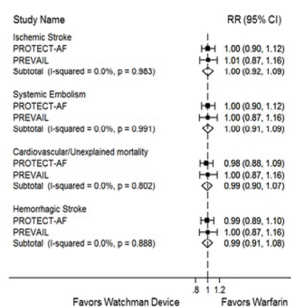
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**Background:** Recent RCTs indicate non-inferiority of percutaneous left atrial appendage (LAA) closure compared to warfarin for stroke prevention. The use of percutaneous devices remains controversial due to concerns for complications. We sought to pool the published data to compare LAA closure vs warfarin.

**Methods:** Medline was searched for RCTs from inception through July, 2014 and meta-analyses were performed using fixed/random effects model as appropriate.

**Results:** Among 2 RCTs, a total of 660 devices were implanted in 732 patients with a 2199 person year (PY) follow-up, implant failure rate of 6.9 [95% Confidence interval (CI): 3.7-12.5] per 100 attempted procedures. As compared to warfarin, LAA closure was non-inferior in reducing ischemic stroke (IS) and systemic embolism (SE), RR for IS was 1.00 [95% CI: 0.92-1.09] and SE was 1.00 [95% CI: 0.91-1.09] respectively (Figure, Panel A). The adjusted incidence rate IS was 1.6 per 100 PY [95% CI: 1.0-2.3], rate of SE was 0.1 per 100 PY [95% CI: 0-0.5], rate of cardiovascular or unexplained mortality was 1.2 per 100 PY [95% CI: 0.6-3.0] and rate of hemorrhagic stroke was 0.1 per 100 PY [95% CI: 0-0.5] in the LAA closure arm. The rate of serious pericardial effusions, major bleed and all complications decreased over time (Figure, Panel B).

**Conclusion:** Results from our meta-analysis suggest non-inferiority of LAA closure compared to warfarin. There has been reduction in implant failure rate and complications associated with LAA closure over time.



**A**  
WATCHMAN vs Adjusted dose warfarin for stroke prophylaxis in non-valvular atrial fibrillation.

| Complication Rates           | Incident rate     | Lower 95% CI | Upper 95% CI |
|------------------------------|-------------------|--------------|--------------|
| <b>Pooled rate</b>           | <b>8.3</b>        | 6.4          | 10.6         |
| Any complication             | PROTECT AF (2009) | 9.9          | 7.5          |
|                              | PREVAL (2014)     | 3.7          | 2.0          |
| <b>Pooled rate</b>           | <b>4.0</b>        | 2.7          | 5.8          |
| Serious pericardial effusion | PROTECT AF (2009) | 4.8          | 3.1          |
|                              | PREVAL (2014)     | 1.9          | 0.8          |
| <b>Pooled rate</b>           | <b>1.4</b>        | 0.2          | 11.2         |
| Major bleeding               | PROTECT AF (2009) | 3.5          | 2.1          |
|                              | PREVAL (2014)     | 0.4          | 0.1          |
| <b>Pooled rate</b>           | <b>0.6</b>        | 0.2          | 1.5          |
| Device Embolization          | PROTECT AF (2009) | 0.4          | 0.1          |
|                              | PREVAL (2014)     | 0.7          | 0.2          |
| <b>Pooled rate</b>           | <b>1.0</b>        | 0.5          | 2.0          |
| Procedural Stroke            | PROTECT AF (2009) | 1.1          | 0.5          |
|                              | PREVAL (2014)     | 0.7          | 0.2          |
| <b>Pooled rate</b>           | <b>6.9</b>        | 3.7          | 12.5         |
| Implant Success rate         | PROTECT AF (2009) | 9.1          | 6.8          |
|                              | PREVAL (2014)     | 4.8          | 2.8          |

**B**  
Complications rates and Implant success rate with Watchman implant.