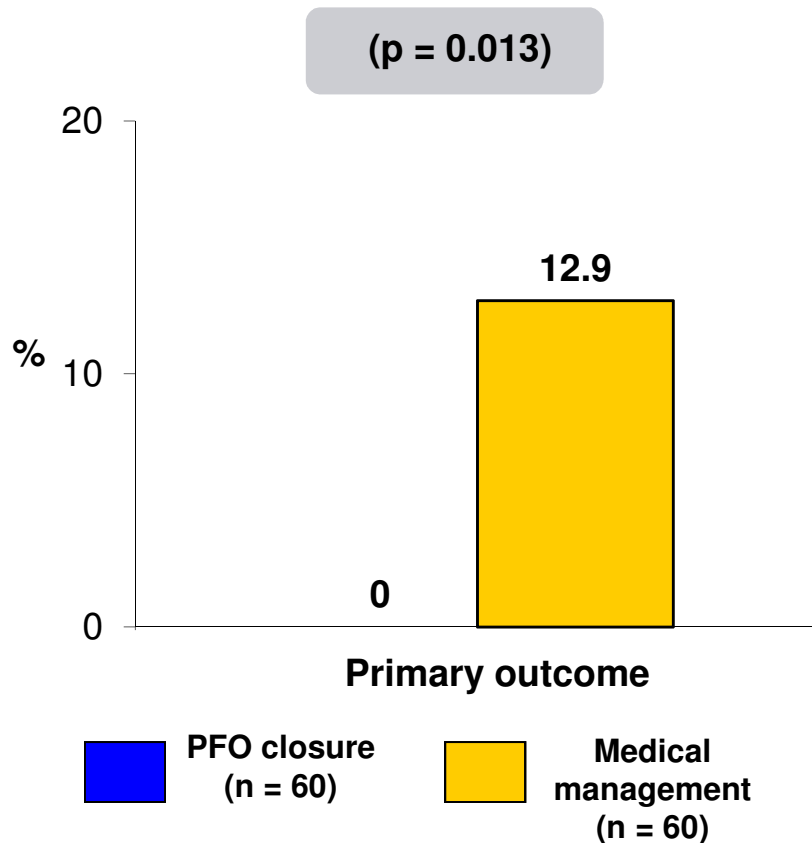


DEFENSE-PFO

Trial design: Patients with high-risk PFO were randomized in a 1:1 fashion to either PFO closure with the Amplatzer PFO Occluder or medical management. Patients were followed for 2 years. The trial was terminated early.



Results

- Primary outcome, stroke/vascular death/TIMI major bleeding over 2 years: PFO closure vs. medical management: 0 vs. 12.9%, p = 0.013
- Ischemic stroke: 0 vs. 10.5%, p = 0.023; hemorrhagic stroke: 0 vs. 2.5%, p = 0.3; TIA: 0 vs. 2.0%, p = 0.32
- New ischemic lesion on MRI: 8.8% vs. 18.4%, p = 0.24

Conclusions

- PFO closure among patients with cryptogenic stroke and high-risk PFO (atrial septal aneurysm, hypermobility, or large size) was superior to medical management alone in reducing the primary endpoint including recurrent ischemic strokes up to 2 years of follow-up
- Although terminated early, overall results were similar to recent trials supporting PFO closure