PFO Closure in the Gore REDUCE Clinical Trial: Primary Results

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Disclosure of Financial Interest

- SEK, LS, JFR, and LT are national principal investigators for the REDUCE study and are compensated for their time by the sponsor, W. L. Gore & Associates.
REDUCE Study

- **Aim:** establish superiority of PFO closure in conjunction with antiplatelet therapy over antiplatelet therapy alone in reducing the risk of recurrent clinical ischemic stroke or new brain infarct.

- **Randomized, controlled, open-label trial**

- **664 subjects randomized in a 2:1 ratio to:**
  - **Closure:** PFO closure with GORE® HELEX® Septal Occluder or GORE® CARDIOFORM Septal Occluder plus antiplatelet therapy
  - **Medical therapy:** antiplatelet therapy alone

- **63 sites in 7 countries**
  - Canada, Denmark, Finland, Norway, Sweden, UK, US
REDUCE Study Design

Medical Therapy

• Antiplatelet standardized options:
  • Aspirin alone (75-325 mg once daily)
  • Combination aspirin (50-100 mg) and dipyridamole (225-400 mg)
  • Clopidogrel (75 mg once daily)
  • Other combinations or the use of anticoagulants was not permitted

• Prescribed for all subjects for the duration of the study
• Each site was expected to treat all subjects with the same antiplatelet therapy

Follow-up

• Followed for up to 5 years
• Neurology assessments at 1, 6, 12, 18, 24, 36, 48, and 60 months
• Closure group also had echo with bubble study at 1, 12, and 24 months
• MRI imaging at baseline and 24 months (if not already performed for an endpoint event)
Co-Primary Endpoints

• Freedom from **recurrent clinical ischemic stroke** through at least 24 months

• Incidence of **new brain infarct** (defined as clinical ischemic stroke or silent brain infarct*) through 24 months

*New T2 hyperintense MRI lesion with diameter $\geq 3$ mm; adjudicated by MRI core lab