DOES PATIENT SELECTION MAKE THE CLOSURE STUDY LESS APPLICABLE?

ACC Moderated Poster Contributions
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Background: Percutaneous closure of patent foramen ovale (PFO) in patients with incident cryptogenic stroke or transient ischemic attack remains controversial. Despite registry data suggesting considerable advantage of closure over medical therapy, the CLOSURE trial showed no benefit. This discrepancy is unexplained, but could relate to patient selection.

Methods: To assess impact of patient selection, we compared patients enrolled into CLOSURE at our institution to off-label closures performed during the same time period. Transesophageal echocardiograms from both populations were reinterpreted by 2 blinded readers to assess PFO morphology.

Results: Between 11/5/03 and 4/16/07 there were 100 off-label closures and 33 patients randomized into CLOSURE I. Compared with off-label closure, patients in CLOSURE I were younger (41.6+10.1 vs. 50.0+14.0, p=0.0005) and had fewer cardiovascular risks including hypertension (6% vs. 36%, p=0.0007), hyperlipidemia (24% vs. 52%, p=0.008) and prevalent coronary disease (3% vs. 44%, p<0.0001). Baseline hemoglobin was lower in off-label closures (14.5+/-1.3 vs. 13.7+/-1.7, p=0.018). Though most echocardiographic comparisons were underpowered, degree of right-to-left shunt was considerably higher in off-label closures (28/14/58% vs. 45/30/25%, mild/moderate/severe, p=0.026). The degree of shunting in our CLOSURE patients was similar to that previously reported for the entire study.

Conclusion: Off-label closures outnumbered patient recruitment into CLOSURE 3:1 during the recruitment period. Though certain demographic differences were expected (age >60 was an exclusion for CLOSURE I), vascular risks were considerably greater in the off-label group and may be important mechanistically for future stroke risk. The greater frequency of large shunts, in particular, suggests that higher-risk patients may have been preferentially closed off-label. These results suggest that CLOSURE findings may not apply to all patients with initial cryptogenic stroke and that future studies of device closure could benefit from fewer exclusion criteria.