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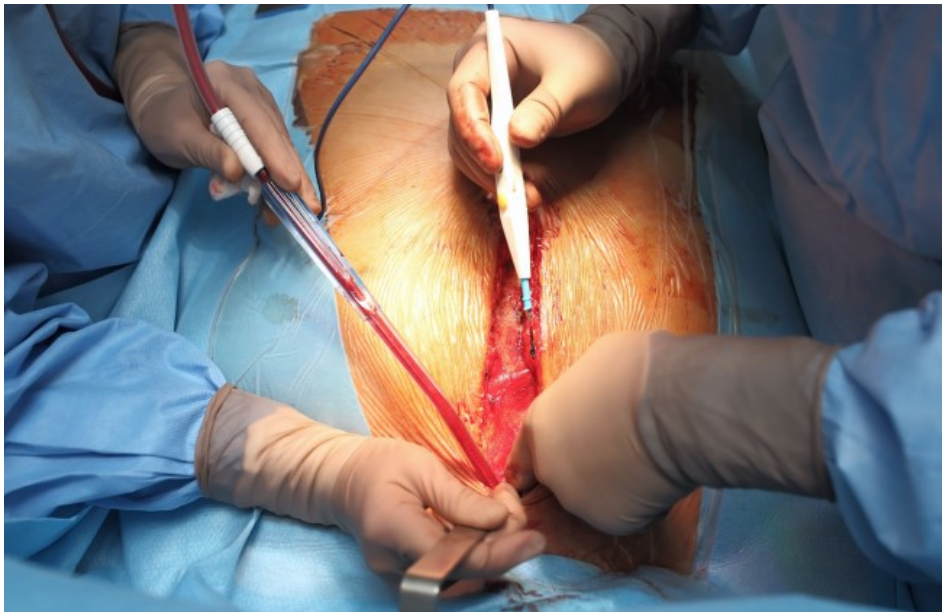
Largest Study to Date Supports Surgical LAA Closure in A-fib Patients

Among patients having other cardiac surgeries, LAA closure cut thromboembolism risk, most notably in the absence of anticoagulants.

By **Shelley Wood** *January 23, 2018*



Another study, this one drawing on data from the Society of Thoracic Surgeons (STS) Adult Cardiac Surgery Database, supports a role for left atrial appendage occlusion (LAAO) during cardiac surgery as a means of preventing thromboembolism in adults over the age of 65 with atrial fibrillation.

The reduced risk of thromboembolism among patients treated with surgical LAAO was seen in those discharged without

anticoagulation, but not in those given prescriptions for anticoagulants at discharge.

“These findings support the use of surgical LAAO, but randomized trials are necessary to provide definitive evidence,” investigators led by Daniel J. Friedman, MD (Duke University School of Medicine, Durham, NC), conclude. “To our knowledge, this study represents the largest study assessing long-term outcomes of LAAO by any method.”

Speaking with TCTMD, senior author J. Matthew Brennan, MD (Duke University School of Medicine), took an even stronger stance. “From my perspective, the standard of care really should move towards closure unless there is a clear reason not to do so,” he said. “I mean that to be provocative, but I say that because it’s not just a single study. There are now multiple smaller studies that have showed a benefit of closure, plus the small randomized study presented at last year’s ESC. So you are starting to see a really consistent message.”

If it “were me or my family member” undergoing cardiac surgery, Brennan continued, and the surgeon recommended closure and asked: “Do you want the LAA closed? The answer is going to be yes.”

Brennan, Friedman, and colleagues published their findings this week in JAMA.

Surgical Closure Under-studied

Transcatheter approaches to LAAO have been studied in randomized clinical trials—with mixed results—and one such device, the Watchman (Boston Scientific), holds US Food and Drug Administration approval. Surgical LAA closure, on the other hand, has not been studied in large randomized trials, and whether or not to perform LAAO has long been a matter of surgeon preference and practice patterns. Both European and US guidelines give the procedure a Class IIb recommendation (“may be considered”), Friedman et al note.

For the current study, Friedman and colleagues reviewed a nationally representative Medicare-linked sample of patients who underwent cardiac surgery between 2011 and 2012. All patients were 65 or older, and the surgeries included CABG, mitral valve surgery, and/or aortic valve surgery with or without surgical LAAO.

Among the more than 10,500 A-fib patients who underwent surgery during the study period, 3,892 also underwent LAAO. At a mean follow-up of 2.6 years, the primary endpoint of thromboembolism (defined as stroke, transient ischemic attack, or systemic embolism) occurred in 4.2% of patients who had received LAAO compared with 6.2% who had not (HR 0.67; 95% CI 0.56-0.81). Rates of all-cause mortality as well as a composite endpoint of thromboembolism, hemorrhagic stroke, or all-cause mortality were also higher among patients who did not undergo LAAO, findings which also held up after adjustment.

In additional analyses, the rate of thromboembolism among patients who had undergone LAAO and who were discharged on anticoagulation was not statistically different than that among patients who did not get LAAO. In patients not discharged on anticoagulants, however, thromboembolism rates were significantly higher: 4.2% versus 6% (HR 0.72; 95% CI 0.53-0.97).

Anticoagulation Concerns

In an editorial accompanying the study, Victor A. Ferraris, MD (University of Kentucky, Lexington), points out that patients' anticoagulation status in the series was assessed at discharge and does not take into account whether patients were prescribed some form of anticoagulation later on, potentially muddying this important finding. Nevertheless, he continues: "In the anticoagulation subset, there is a strong signal that surgical LAAO may be equivalent to anticoagulation prophylaxis to avoid thromboembolism in certain patients. This possibility is intriguing because it suggests that surgical LAAO may be as effective as anticoagulation and could potentially avoid the bleeding risks associated with anticoagulation."

To TCTMD, Brennan congratulated Ferraris for picking up on what he believes is the most important next step, namely a randomized study that specifically assesses anticoagulation use following closure. He'd like to see a study in which all patients with suitable anatomy had their LAAs closed during open heart surgery and then were randomized to anticoagulation or no anticoagulation. The potential pool of people who could benefit is not restricted to patients who can't take long-term anticoagulation, he noted, pointing out that it's not always possible to predict who is going to develop post-op bleeding. There's also the much larger pool of people who would prefer not to take blood thinners long-term, he added.

One thing that can't be pulled from the STS database is information on what technique was used for LAA occlusion, Ferraris observes in his editorial. That's important because incomplete or ineffective closure procedures have been linked to an increased risk of thromboembolism. "Any future randomized trial would have to measure the effectiveness of LAAO at various times after operation and this necessity adds to the complexity of any future trial design," Ferraris writes.

That's a point also made by Sameer Gafoor, MD (Swedish Heart & Vascular Institute, Seattle, WA), who commented on the study for TCTMD. He referenced the ongoing Left Atrial Appendage Occlusion III Study, cited by Friedman et al in their paper, which is randomizing 4,700 cardiac surgery patients with A-fib to surgical LAAO or no LAAO and tracking the incidence of stroke or systemic embolism out to 4 years.

"One of the things that would be great to see from this study would be imaging follow-up at different points after the surgical closure," Gafoor said. "Adding that would help us identify which patients could potentially come off anticoagulation."

According to Gafoor, the current paper "adds to what we already know: that LAAO helps reduce the risk of thromboembolism, whether that's surgical or transcatheter." The study doesn't speak to whether one approach is better than another, he clarified; rather, "it shows that the concept of closure is sound."

Brennan, for his part, agreed that the study adds to the evidence base supporting closure more generally for stroke prevention, but stressed that these data specifically support closure in people who are already undergoing surgery for another cardiac indication and not as a stand-alone procedure. "I also think there are some advantages to closing the appendage from the outside rather than leaving an in-dwelling device in place, like the Watchman," he cautioned. As such, the surgical closure data cannot be fully transported "over to the percutaneous world," Brennan concluded.

Sources

Friedman DJ, Piccini JP, Wang T, et al. Association between left atrial appendage occlusion and readmission for thromboembolism among

patients with atrial fibrillation undergoing concomitant cardiac surgery. JAMA 2018; 319:345-347.

Ferraris VA. Left atrial appendage occlusion during cardiac operations for prevention of thromboembolic events. JAMA 2018; 319:365-374

Disclosures

Friedman reports receiving grants from Boston Scientific, Abbott, the National Cardiovascular Data Registry, and the NIH.

Brennan reports holding an Innovation in Regulatory Science Award from Burroughs Welcome Fund and a grant from the Food and Drug Administration.

Ferraris reports having no conflicts.

Gafoor reports consulting for Boston Scientific and Abbott.