**Title: AFSymposium 24: EMERGE LAA Post-Approval: Amulet LAA Occluder in US**

**Participants: Dr Christopher Ellis**

**Date: 07 Feb 2024**

**Dr Christopher Ellis**

"Hi, I'm Dr. Christopher Ellis. I'm a professor of medicine at Vanderbilt University Medical Centre, and I'm speaking on behalf of my co investigators with the EMERGE LAA study, which we presented at the AFIB Symposium here in Boston in 2024.

What is the background of this study?

So, background of the study: the amulet device is a left atrial appendage occlusion device, similar to the Watchman device, which is used to help reduce the chances of embolic stroke from AFib, specifically for people who are high risk for bleeding. And so that device has been utilised in Europe for many years prior to the FDA approval of the device. After the amulet IDE here in the United States and abroad, that was FDA approved in 2021.

Can you please tell us about the study device?

So once the device got out for commercial use in the United States, part of the obligation for implanters was to be trained appropriately to learn the new device, and then also to enter the data from their implants into the NCDR registry for LAA occlusion devices.

And so the EMERGE data is basically the first 500 patients that were implanted with amulet in the United States since commercial launch up to the end of December of 2022. We will collect additional data all through the implants in 2023. So there'll be over 10,000 patients under study, with up to three to five-year clinical endpoint follow-up.

What was the methodology of this study?

The study design is essentially we called the information from NCDR registry on patient information, the procedure details and a 45-day follow-up, and then looked at major or significant adverse events that occurred in the first seven days after implant, or up to 45 days. We don't have data in the EMERGE LAA for longer-term follow-up beyond 45 days, but this was generated largely just from the NCDR registry database.

What data did you present at AFSymposium?

So we presented that since commercial launch up to the end of 2022, over 5500 patients had been implanted with amulet in the United States by a variety of experience levels for operators and those that had done ten or less procedures. We characterise as low-volume implanter moderate experience would be ten to 30, and then the highly experienced operator 30 and beyond.

So we looked down at all of the significant adverse events, the closure rates and the procedure efficacy for the total cohort, and then also broke down by experience level of the operators.

What are the key messages for practice?

Some of the key findings are that as people gain more experience with the device, they tend to have better occlusion. They'll have reduced procedure time, reduced contrast load, all indicating more understanding of the device and having smoother, shorter procedure times. Hopefully that also translates into lower peri-procedural risk. We did see slightly lower levels of pericardial effusion at implant and delayed pericardial effusion, which was a significant concern that had been brought up before about the amulet design. And the data looks better now in commercial use than it did in the amulet IDE trial. So we think as people are gaining more experience with it and we're putting in more of a rigorous training protocol and rolling it out carefully in the United States, we're seeing improvement in those risk components while maintaining really good closure.

So 97% of patients were effectively closed with the device with zero to two millimetres of peridevice leak, and over 85% of patients had zero leak. The vast majority of patients went home or discharged off oral anticoagulation. So the device seems to be performing a little better in the registry than it did in the clinical trial.

So with that, I think that the experience level is a key factor. So getting through the learning curve from zero up to 30 cases, you'll obviously have better comfort level with the device and likely safer and shorter procedures to implant the device, but also that there's still work to be done because the major adverse event rate was about 0.7% in the total cohort, and we want to continue to drive that closer to zero.

What are the next steps?

Next steps on this: The post-implant drug regimen is labelled in the United States for dual antiplatelet therapy up to six months after implant. That's potentially changing with future trials like the catalyst trial, and potentially with additional device design changes in the future. So that's a short-term exposure to either antiplatelet or antithrombotic medicine after the device goes in to help prevent thrombus on top of the device, the rate of that is still pretty low. It's like 2% or so in the IDE, and that was not something that was reported in the EMERGE LAA study, so there's still more investigation to do on that.”