- I'm James Freeman, I'm a cardiac electrophysiologist at Yale and I direct our EP laboratories at Yale, and today I'll be talking about our study on in-hospital outcomes after left atrial appendage closure with the Watchman 2.5 Device, the first generation device, and the Second-Generation Watchman FLX Device.

Importance of this study

Yeah, so the Second-Generation Watchman FLX Device was launched... It was commercially released in 2020, in August of 2020. And we really were interested in looking at the outcomes of that procedure relative to the first-generation device, in particular, looking at adverse event rates and then metrics of acute procedural success.

Key differences between the studied devices

So there were some really important differences between the two devices. Boston Scientific, essentially, closed the end of the device. And that enabled them to create a flex ball which is this atraumatic ball, when the device is partially deployed, so that you can put the device in, advance it in, and position it in multiple different ways to try and get optimal positioning. And then also the device can be easily recaptured and repositioned a number of times. They also had a couple other advancements, they have a dual row of anchors and extended a mesh coding a little further down on the device. The device was largely redesigned to try and minimise any trauma associated with placement and to decrease the rate of pericardial effusion, which was a historic Achilles heel of this procedure.

Study design and patient baseline characteristics

So, the Watchman FLX Device was commercially released beginning in August of 2020. And the way they did the commercial rollout was fairly unique. They essentially went to each site, and they asked them to turn in their inventory of the old device and use, exclusively, the new device within a month, in almost every case. And so that presented us with a really unique opportunity to do a natural experiment error analysis. So the way that worked is that at any given site if they had done 35 Watchman FLX cases, we looked at the 35 cases of the Watchman 2.5 that they had done immediately proceeding the first flex case. And so each site served as its own control, and really nothing else was changing at those sites at the time, the indications for the procedure were the same, the operators were the same, the sites were the same. There were no other big, secular trends happening at the time, and so we thought this offered us an opportunity to really get balance between the two different groups. And we ended up with about 27,000 patients, in both groups, over a relatively short time horizon. And so the result of that was that when you look at the baseline characteristics between the patients that received the Watchman FLX and those that received Watchman 2.5, the groups were essentially identical. It was a akin to what we see in a randomised trial, the difference being that we have 27,000 people in each arm. So it has all the advantages of a randomised trial and that you have real balance between the two groups, and so any differences we're seeing are not differences associated with the groups being different but really with the procedure. We then did a secondary analysis which was a propensity-score-matched analysis. And that we took all of the Watchman FLX patients and we did matching on age, gender, propensity score, actually, up to two patients with the Watchman 2.5, and used that analytic methodology to recapitulate the same efforts to try and look at at outcomes between the two procedures.

Key findings

Yeah, so for secondary endpoints, we looked at acute procedural success metrics and we found that acute procedural success, so the number of devices that were successfully deployed and released, was higher by about a percent. And so I think that speaks to the fact that this device is a little easier to to deploy and to optimise positioning, and so I think to a big advantage. We saw a decrease in procedure time by about four minutes, associated with the new device, and we think that that's important. And it was a non-significant finding, but different in absolute numbers, we saw a lower rate of leaks greater than five millimetres. Again, possibly speaking to the fact that we can optimise positioning of this device. Also, the device has a little more metal in it that should allow it to conform to appendages a little better in theory, and this data seems to suggest that that's the case with some of the leak data.

Correlation between procedure volume and safety events

So the key finding is that the device is markedly safer, and the rate of major in-hospital adverse events dropped from 2.4% to 1.35%, and that was largely driven by a market drop in pericardial effusion requiring intervention. So the rate of pericardial effusion requiring intervention dropped from 1.2% to 0.4%. And that's a really catastrophic complication with a lot of downstream consequences. So as a result, the rates of major bleeding were markedly lower, and rates of major bleeding were also lower potentially for other reasons, but we really think it was largely driven by pericardial effusion. The rate of death was cut in half so from 200,000 to 100,000. Rate of cardiac arrest decreased as well. So I think they really move the needle with this device iteration on procedural safety.

Take-home messages for clinicians

Yeah, so the key take-home message here is that the procedure has gotten markedly safer with the new device. And in particular one of the main Achilles heels of the procedure was pericardial effusion requiring intervention, and there's just a market decrease in that catastrophic complication. So I think they've really changed the risk benefit calculation for patients and for physicians as they contemplate this procedure. And I think it's really important to note that this procedure's often done in people that are older and relatively ill. You know, the average age of people getting this procedure done in the United States is 76, the average CHA2DS2-VASc Score is is 4.6. So these are high-risk patients. So to be able to cut procedural safety, or to improve procedural safety that much is really a big deal.

Next steps

Yeah, so I think they'll continue to be iterations of devices and whatnot. We need to look at post-procedural anticoagulation and antithrombotic strategies to try and continue to improve the safety of the procedure. We actually have some work that's coming out on on post-procedure antithrombotic, and the ability to try and prevent bleeding in this very-high-risk population. So I think a lot of exciting work to be done in this space to try and optimise the procedure and make it even safer and better.