radcliffe cardiology

Title: EHRA 24: FIH Clinical Series of Conformable "Single Shot" PFA Catheter for PVI
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Dr Vivek Reddy

"I'm Vivek Reddy from the Mount Sinai Heart Hospital in New York City, and I'm going to discuss the trial results that we just presented at the late-breaking session of EHRA 2024.

Overview of PulseFit Ablation

PulseFit ablation is transforming our care of atrial fibrillation, and it has a lot of advantages. We're very happy with it as a general approach. However, there are a few limitations. One of them is the workflow, which, while substantially better than thermal ablation, could still be improved a little bit. Second, while the durability of our ablation lesions has been quite good with PulseFit ablation, it's not perfect, so we still have some room for improvement.

The Trial

In this trial, which was a first-in-human trial, we used this single-shot PulseFit ablation catheter. This particular catheter is unique because it is a lattice framework that's conformable. The idea is that this device can actually morph to the tissue. It also has a few other interesting capabilities. It's linked to an electronatomical mapping system, so many of the things that we do, we can do with less fluoro exposure, as well as creating an anatomical shell to help better define where we want to place the lesions. This particular catheter also has mini electrodes so that you can actually map the electrical potentials. You can look at the potentials before ablation, and at the end of the procedure, if desired, you can create an electronatomical map to identify exactly where your lesion set was.

Study Design and Methodology

This was a first-in-human study and was a single-arm study. It was conducted at three centers in Europe: two in the Czech Republic and one in Lithuania, with multiple operators—six different operators. While it was a single-arm study, it included a one-year follow-up with Holter monitors at six months and one year, as well as transtelephonic monitors that were done both weekly and for symptoms. One of the unique aspects of the trial, which I think is one of the most important aspects, is that the protocol had a protocol-driven invasive remapping procedure around 75 days after the index procedure. This allowed us to assess the durability of the lesion set.
Because of the way the trial was designed, we went into the procedure with one pulse waveform. Over the course of the trial, as we gathered remapping data, that waveform evolved from the first waveform to the third waveform, which gave us the best results.

Results

The trial was conducted in 85 paroxysmal AFib patients. From a safety perspective, the catheter performed extremely well, with zero major safety events in these 85 patients. From a performance perspective, it was quite good. There was 100% pulmonary vein isolation in all patients, achieved with a total of ten minutes of transpired ablation time. That is the time from the beginning of the first lesion to the end of the last lesion. The total left atrial dwell time of the catheter was approximately 20 minutes, the total procedure time was 60 minutes, and the total fluoroscopy time was an average of six minutes.

Effectiveness and Durability

In terms of the effectiveness of the procedure, beyond the acute PV isolation, the clinical effectiveness was quite good. In the full cohort, the success rate at the one-year time point was approximately 82%. However, probably the most interesting aspect is the durability. With the final waveform, when we did the invasive remapping, we had 99% durability on a per-vein basis and 96% on a per-patient basis. These are quite encouraging results that we were happy with.

Next Steps

When we think about the next steps, we must consider some limitations of the trial, such as the relatively limited number of operators, centers, and patients. The next step is to conduct this same sort of study in a much larger population with more operators, more patients, and more centers.