Title: Conformable PVI Catheter for PVI
Participants: Dr Vivek Reddy
Date: 18th April 2023

Dr Vivek Reddy

"- I'm Vivek Reddy from the Mount Sinai Hospital in New York City, and I'm going to discuss our future abstract on the conformable PVI ablation catheter.

Research Context and Study Rationale

So let's talk about the background of this catheter first. There's a conformable, what we call a lattice-tip catheter that's a focal catheter that is just recently received CE Mark approval. The catheter is an 8 French catheter, so it fits in most of our sheaths, but the tip is a nine millimetre mesh. And one of the interesting things about the catheter is when we're doing point by point ablation, because it conforms somewhat to the tissue the stability seems to be quite good, the interaction with the tissue seems to be quite good. Now, one of the other interesting aspects is the company said, "Well, this is an interesting type of catheter." But the field also wants a single shot PV isolation tool, a tool that you can just sort of push up against the vein and it touches the vein, and you just deliver one lesion to isolate the vein. So that was the idea behind this conformable PVI catheter, to create a type of catheter that's highly deformable, a meshlike catheter that can accommodate different types of pulmonary vein anatomies, different pulmonary vein sizes, push it up against the vein and then deliver pulse electric field energy to isolate the pulmonary vein.

Overview of the SpherePVI Catheter

One of the interesting things about this catheter is that it's an over-the-wire catheter, which is useful for engaging pulmonary veins, but also it's linked to an electroanatomic mapping system, so it is magnetically localised in the mapping system. So you can move the catheter around in the chamber to create the anatomy quickly, then engage the veins, isolate the veins, and at the very end if you want to do additional ablation,

perhaps with a different catheter even, you have that flexibility that's the design of this technology.

Study Design, Outcome Measures and Eligibility Criteria

This is a first in human clinical trial, this is the first time this catheter is being used and is being conducted at at least three centres in Europe. I say at least because we've started in three centres, but more are likely to be included. The total trial design is up to 160 patients with paroxysmal atrial fibrillation who failed somewhere between a class 1 to a class 4 antiarrhythmic drug. These are patients who will undergo the procedure. After the procedure, one of the unique aspects of this trial design is that patients are planned for a three month remapping study. So not because of symptoms, but rather to understand the quality of the ablation lesion and to do additional touch up if necessary, the patients will come back for an invasive procedure at three months. The veins will be checked to make sure they're all isolated, or if not, try to understand why and improve everything. In addition, in a subset of the patients, there'll also be post-procedure brain MRI imaging to look for asymptomatic cerebral ischemic events as well as post-procedure endoscopy, esophageal endoscopy to verify the absence of effect on the oesophagus. The efficacy endpoints will, of course, include acute pulmonary vein isolation, but also the success, clinical success out to one year after a three month blanking period. And certainly on the safety side, there's a composite safety endpoint that includes all potential complications as typical for AF ablation studies.

Next Steps

So the trial is ongoing at this point, patients are being enrolled at three centres and then ultimately at more centres. Once the 160 patients are enrolled and followed out to one year, then we'll be presenting these data hopefully at a conference like this."