radcliffe vascular

Title: LINC 23: AVPAS: Lutonix AV Post-Approval Study
Participants: Dr Scott Trerotola
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Dr Scott Trerotola

"My name is Scott Trerotola. I'm the chief of interventional radiology at the University of Pennsylvania Medical Centre in Philadelphia, Pennsylvania.

Reasoning Behind this Post-approval Study

Post-approval studies can be required by the United States Food and Drug Administration as follow-up after pivotal trials, in this case, the Pivotal IDE trial for the Lutonix PTA balloon and drug-coated balloon. And usually, they're required because of considerations regarding sometimes safety. In this case, the trial finished at a time when the safety of Paclitaxel was being questioned after the Katsanos paper and the FDA wanted more numbers, they wanted to see just more patients. And that's very common. So really, although as I'll mention, there really aren't any safety concerns at this point, I think that was probably one of the more compelling reasons for the FDA to want to see more patients in this study.

Lutonix PTA Catheter and its Unique Feature

The Lutonix PTA or DCB, drug-coated balloon catheter is one of a class of DCBs that are most of which have paclitaxel on them. This one has a dose of two micrograms per millimetre squared, so it's at the lower end of the dose range for these devices. It like all the other devices, as far as I know, has a low-pressure compliant balloon as opposed to the high-pressure balloons we use for angioplasty with POBA. It has an excipient which is polysorbate, which again differs from some of the other devices. So, each of these devices is unique, although all of them have in common that they're using this antiproliferative drug to try to reduce restenosis.

Study Design and Patient Population

So, this post-approval study is a single arm study looking at the exact same patient population as the Pivotal Randomised IDE trial did. These are patients with functional AV fistulas that are in use but failing due to any number of factors except for thrombosis with a stenosis anywhere from the anastomosis to the end of the terminal arch of the cephalic vein, so up until but not including central veins.

Key Findings Revealed at LINC 23

So, the FDA requires interim analyses during the study. This was a planned interim analysis. The study will enrol 213 patients. This was 81 patients. And because of that interim analysis, we had an opportunity to look at interim results, keeping in mind that these are just interim results, but we do have both safety and patency data on those first 81 patients.

Impact of Findings on Clinical Practice and Future Research

The findings that we reported for patency were, a six-month target lesion primary patency of 77.6%, which is better than we saw in the IDE trial and is on par with what is being seen in some of the other trials, including the IN.PACT trial. So, in this more real-world study still, with all the trappings of a serious clinical trial, including a core lab adjudication of lesions and very careful follow-up patients, we've seen better patency than we saw in the IDE trial, which, as you probably know, was a negative study. So, I'm very encouraged that we're seeing results that look like they're benefiting patients. We did see some benefit in the IDE trial in terms of improved time to restenosis, prolonged time to restenosis, as well as reduced number of interventions to maintain target lesion primary patency. And here we're seeing what look like good patency numbers as well. The safety data are excellent.100% have met the safety goals. So really, at this point, I don't think there’s any concern among any of these devices about safety. So, we're seeing good patency, we're seeing good safety, and I think this device does benefit patients.

Further Study Needed

We’re at the point when we finish this study, we will have enrolled over 800 patients with Lutonix DCBs in carefully controlled, designed clinical trials. Some controlled, randomised controlled, some single-arm trials. We have looked in all those trials at lesions all over and including in the global registry, we had grafts as well. So, one thing we have been able to do is sort out whether individual areas of stenosis and or individual stenosis types as determined by ultrasound, for example. Some great work from Kate Steiner in the UK. Also, we are starting to look at the possibility of genetically, genetically typing these like we do in cancer, so that we might be able to geta sample and say, okay, this lesion is going to respond to a DCB, or this lesion needs something else like a covered stent. This lesion may respond just a plain old balloon angioplasty. And that kind of personalised medicine we're going to get to, we're just not there yet.