- So I'm Nick Shammas, I'm the president and research director of the Midwest Cardiovascular Research Foundation. And I'm also interventional cardiologist by training.

Aim of This Study

So the JET-RANGER Study evaluate the Jetstream Atherectomy device. It's a rotational and aspiration device as a vessel prepping device prior to drug-coated balloon versus just drug-coated balloon alone. The idea is to demonstrate whether there's any added value for vessel prepping using the Jetstream device on top of the drug-coated balloon that have been of course proven to be quite effective.

Inclusion and Exclusion Criteria

Yeah, so the primary endpoint of the study is looking at target lesion revascularization, but again as we all know that vessel prepping works best in complex lesions, the inclusion criteria have included patients typically that had longer lesions over 10 centimetre or chronic total occlusion or patients at least with moderate calcification and higher. So we've selected those patients on purpose, so it made the inclusion criteria to include those more complex lesions so we can get the best benefit out of the Jetstream vessel prepping.

Study Design

This was a randomised trial, two to one randomization with Jetstream plus drug-coated balloon versus drug-coated balloon alone. And the drug-coated balloons selected were the Ranger balloon as well as the IN.PACT balloon. So initially it was designed as a superiority study to include a larger number of patients of about 255 patients or so in 11 sites, in the US. And in fact, the 11 sites did enrol patients all of them in that particular study. However, and unfortunately the study had to be stopped earlier just because of poor enrolment due to two reasons. Number one, the warning about the drug-coated balloon and the increase in mortality at five years. And the second one is the COVID pandemic that affected enrolment in multiple sites. So we actually ended up enrolling a smaller number of patients. And I do believe we can qualify the results in that case as more exploratory considering the less enrolment anticipated.

Key Findings

The primary endpoint of the study is looking at target lesion revascularization at one year. The follow up will go on all the way to three years but the primary endpoint is at one year and the target lesion revascularization as an intention to treat analysis was defined as repeating the treatment in the same zone that has been previously treated. But this time we've included stenting as a failure, in other words, stenting happening during the procedure is considered a target lesion revascularization. That was a primary endpoint. The secondary endpoint did not include that. That means target lesion revascularization start to be counted post index procedure or post discharge. But looking at the primary endpoint this study showed a significant reduction in bailout stenting which led actually to a statistically significant less target lesion revascularization in the Jetstream Atherectomy arm compared to the DCB arm alone. And in fact, the freedom from target lesion revascularization at one year was a hundred percent and that's 11 sites enrolling in the Jetstream plus DCB versus less than 50% freedom from TLR and the PTA arm. And that's mostly accounted for by the fact that bailout stenting was very high in the PTA arm alone or the DCB arm alone. About 50% of those patients required stenting. Remember these are complex lesions and that high bailout stenting is not a surprise.

Conclusions

Well, Jetstream Atherectomy clearly is a powerful vessel prepping device that leads to less stenting. And we've demonstrated that very clearly in this study. And I believe that supports previous data and this time in a more randomised fashion in multi-center trial. And that is an important finding for the strategy of leaving the least behind. So using that device, particularly in zones where you do not want to see a stent, like the common femoral artery or the distal SFA or the popliteal arteries. This would be an excellent device to use with very, very good outcome. And you do not have to really use a stent in that regard, as long as you combine that device with the drug-coated balloon specifically here in this trial it was either the Ranger or the IN.PACT balloon.

Next Steps

Well, we would like to see a larger randomised trial to confirm this data. And I think it may very well considering how excellent the early data with the Jetstream and DCB maybe something looking at potentially comparing some of that data to primary stenting with a drug-eluting stent. I think these are two different strategies but I believe the data that we have seen in this particular trial may very well create a very strong competitor to the primary drug-eluting stenting and offer a new strategy for patients where you leave the least amount of metal behind.