- Hi, good morning! I'm Mehdi Shishehbor. I'm an interventional cardiologist and the president of the Harrington Heart & Vascular Institute here in Cleveland at University Hospitals.

Aim of the Study

The aim of this study was to evaluate the safety and the efficacy of the Chocolate Touch balloon, a second-generation drug-coated balloon, versus the first-generation Lutonix DCB, which was approved as the first DCB balloon over five or six years ago.

The Chocolate Touch DCB

The Chocolate Touch DCB is a special balloon, it's a second-generation drug-coated balloon, especially because of some of its structural features. Unlike traditional balloons, which are just a balloon by themselves, the Chocolate Touch has two components. It has a balloon but it also has a nitinol cage that creates grooves and pillows between the balloon. These grooves and pillows allow differential dilatation and that differential dilatation is what we believe leads to lower dissections and less vessel trauma. It also allows a higher surface area for drug delivery, about 20% higher surface area because of those grooves and pillows, which is very beneficial when you're trying to deliver drugs.

Study Design and Patient Population

This was a randomised clinical trial with core lab adjudication and a CEC, independent CEC. Patients were randomised one-to-one to Chocolate Touch and to Lutonix DCB. The follow-up is, obviously, up to five years. We're presenting the 12-month data at ACC. And the primary efficacy endpoint was primary patency, which was defined as having a peak systolic velocity of less than 2.4 without a clinically-driven target lesion revascularisation and without the need for bailout stenting. One of the limitations of prior randomised trials of DCBs have been the fact that many of the patients required bailout stenting but they were still considered a success with DCB. We believe that when you take a DCB approach, you shouldn't be needing to put a stent. So, we wanted to truly assess DCB success so we counted bailout stenting as a failure. Fortunately, none of the patients in the study, in both arms, had bailout stenting. So at the end, this did not become a factor but that's the design and the definition of our primary efficacy endpoint.

Main Findings

The study was very interesting, as we're presenting the 12-month data and what we showed was that Chocolate Touch was non-inferior to Lutonix DCB at one year for primary patency of 78.8% in Chocolate Touch and 67.7 for Lutonix. But importantly, because we met the non-inferiority primary efficacy endpoint, we tested superiority and Chocolate Touch was superior to Lutonix DCB at one year for primary patency. Regarding safety, both devices were equal and there were no differences from the standpoint of safety

endpoint.

Take-home Messages

I think the take-home message from this trial is that, as we evolve and define and innovate with second- and third-generation devices, we need head-to-head clinical trials that can assess efficacy and safety. In this case, the take-home message is that second-generation Chocolate Touch DCB obviously was superior to Lutonix DCB at one year, with better efficacy and similar safety profile. There are obviously features of the Chocolate Touch, as I mentioned earlier, that make it unique and we are interested to see how the results pan out over the mid- to long-term at two, three, and five years.

Ongoing Investigation

As I mentioned earlier, this is an ongoing clinical trial of up to five years. So we will continue to monitor these patients with duplex ultrasound and, obviously, clinical follow-up. Interestingly enough, the study was conducted through difficult times. There was the paclitaxel mortality association which was defined in 2018/2019, which resulted in a six-months hold in the clinical trial here in the United States. And then, as you know, there was the pandemic which really made it challenging to conduct clinical trials in the last two and a half years. But despite all the challenges, we have had 94% follow-up in this clinical trial, at least at one year, and we are hoping that we continue that level of follow-up as we

move on to second, third and beyond. I'm very excited that, as you know in the field of cardiovascular medicine and especially in the field of vascular, there are very few limited head-to-head clinical trials where we are comparing one device against another device, of second-generation versus first-generation. And I'm excited that we were able to embark on this. I'm also very grateful to the international body of investigators and patients that committed in the hard times to do this trial and just fortunate to be presenting this trial and look forward, as I said, to the mid- and long-term results in the future.