Transcript Details

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ReachMD
www.reachmd.com
info@reachmd.com
(866) 423-7849

The Chocolate Touch Study: A Randomized Trial to Confirm the Safety and Effectiveness of Chocolate Touch Paclitaxel Coated PTA Balloon Catheter in Above the Knee Lesions

Dr. Shishehbor:
Hi, I'm Mehdi Shishehbor, president of Harrington Heart and Vascular Institute and I'm honored to be presenting to you today a randomized trial to confirm the safety and effectiveness, of Chocolate Touch Paclitaxel Coated PTA Balloon against the Lutonix in the above knee lesions. These are my conflict of interest.

As you know, there are four drug coated balloons that are currently available in the United States. These have collectively been studied in randomized clinical trials against angioplasty alone and have shown superior efficacy consistently. However, despite this efficacy, these drug coded ballons have a number of limitations. They are associated with acute dissection, requiring bailout stenting, they have significant recoil, because of lack of scaffolding. Frequently, the operators undersized these balloons because they want to prevent dissection and bailout stenting. So, there is minimal acute luminal gain at the time of the intervention, because of under sizing. And we know that the presence of calcium has been a hindrance in drug delivery, With the first-generation drug coated balloons. Chocolate Touch is a special balloon that is constrained by a nitinol cage. Because of this feature, it may address a number of limitations, that I've described to you previously. The nitinol cage in a chocolate balloon creates pillows and grooves. These pillows and groove allow differential inflation, minimizing the sections and vessel trauma. Furthermore, they allow increased surface area by about 20%, which may allow more drug delivery at the time of intervention. Because of these features, we sought to compare the efficacy and safety of the Chocolate Touch DCB, to the commercially available first generation Lutonix DCB in an international randomized clinical trial.

In addition to the features that I described, both balloon have Paclitaxel drug. However, Chocolate Touch has a higher doses per millimeter square, as I've shown you here, and when it comes to sizing of the balloon, because of the features of the Chocolate Touch balloon, it allows with for 1.1 to one sizing versus one to one sizing with Lutonix DCB. This oversizing allows more acute luminal gain, but does not increase the rate of dissection, in previous studies. This was an open-label, randomized, non-inferiority trial of patients with symptomatic SFA, and Popliteal disease, and Rotherfield class three, four and two claudication symptoms. There were 152 patients that were randomized in a Chocolate Touch, and 161 into the Lutonix, in a five-year study. However, I'm presenting the 12-month data today. The primary efficacy endpoint was true DCB success at 12 months, which was primary patency of the peak systolic velocity of less than 2.4, in the absence of clinically driven target lesion revascularization and without the need for bailout stenting. The primary safety endpoint, was a composite of target limb related death, major amputation of the target limb or clinically driven reintervention of the target limb. This was a non inferiority trial for both primary efficacy and primary safety, with a 10% non-inferiority margin. However, this study was powered for sequential superiority testing, If both primary non-inferiority endpoints were met. Trial success was defined as meeting the both primary efficacy and safety endpoints, and the study had 85% power with 230 patients. However, the study ended up randomizing 313 patients into both arms. The principal investigators of this study were myself and Professor Zeller, The Angiographic Core Lab clinical events committee and data safety monitoring board was at Yale Cardiovascular Research Group and at Duplex Ultrasound Core Lab at the Core Lab Black Forest.

This study was again, a randomized clinical trial of 152 patients versus 161. But despite the Paclitaxel association with mortality, and the COVID pandemic, the study completed, 94% follow-up in the Chocolate Touch arm, and a 93.7% in the Lutonix arm. The baseline

characteristics of the patients are shown here. There was a good match between both arms as you can see here. Importantly, there was a good representation of both genders in the study, and majority of the patients at Rutherford three classification claudication. The mean lesion length was around eight centimeter in both arms, there was about 1/5 of the patients with total occlusion and severe calcification, and about 12% of the patients had the use of Atherectomy in addition to DCB as an adjunctive therapy in the trial. There were no bailout stenting in either arm, and no flow limiting dissections. The primary efficacy endpoint, which was non inferiority was met, with a Chocolate Touch a primary patency of 78.8% versus the Lutoix of 67.7% with a P for non-inferiority of less than 0.0001. The primary safety endpoint of non inferiority was also met. Therefore, their superiority was tested, and in this trial, we showed a 12 months that Chocolate Touch second generation DCB was superior to the Lutonix DCB first generation device with a P value of 0.04, and a Kaplan Meier primary patency of 83.3% versus 73% in the Lutonix DCB.

There were a number of prespecified subgroup analysis, which consistently showed Chocolate Touch DCB to be superior to the Lutonix DCB, as I've shown you here for the number of pre-specified subgroup analysis. As I mentioned earlier, Chocolate Touch also met these primary safety endpoints, freedom from major adverse events as described, target limb-related death, major target limb amputation, and target limb reintervention with a non-inferiority P value of 0.0001. Because of the association between Paclitaxel and mortality, there was a post hoc analysis that looked at the rate of mortality in both arms. Blue represents Chocolate Touch DCB and red represents the Lutonix DCB. As you can see, there were no differences in the rates of mortality, up to three years between the two arms of the Chocolate Touch DCB and the Lutonix DCB. Again, the study was not powered to assess mortality, and this was a postdoc analysis.

In conclusion, the Chocolate Touch study met the pre-specified trial success criteria, demonstrating that the Chocolate Touch second generation DCB was non-inferior to Lutonix DCB for both primary efficacy and safety endpoints at 12 months. In sequential testing, we showed that the second-generation Chocolate Touch DCB was superior to the Lutonix DCB. But overall, the study showed the safety and efficacy of Chocolate Touch DCB for the treatment of symptomatic PAD patients with superficial femoral and popliteal artery disease and rotherfield class two, three, and four claudication symptoms. Thank you for your time, and the manuscript was simultaneously published in circulation as part of this presentation.