- I am Bernardo Cortese, an interventional cardiologist from Milano, Italy. My affiliation is Fondazione Ricerca e Innovazione Cardiovascolare from Milano. A foundation which is devoted to clinical research in the cardiovascular arena. Today, we are going to discuss about the late breaking-trial clinical results of EASTBOURNE registry primary endpoint assessment.

Study Background

The background of EASTBOURNE registry is the drug-coated balloon. The novelty in this area is the sirolimus. Sirolimus is a new drug that came out in 2016. So from the very beginning of this new technology by means of Magic Touch DCB we decided to do this prospective registry because we needed to have some good, reliable, clinical data with this new device.

Study Design and Population

The design of the EASTBOURNE study is a prospective registry with central adjudication of all the events, a multi-center study from all around the world. We have enrolled 2,123 patients rendering this the largest study ever done on DCB.

Device Characteristics

The device used in the EASTBOURNE registry is a novel drug-coated balloon eluting sirolimus. And Magic Touch is a DCB which has a new technology, which with the nano-capsule is able to deliver correctly sirolimus to the vessel wall and to keep it there for at least one month. This is the timeline where we want the drug to interrupt the restenotic process.

Key Findings

The key findings are very reassuring in terms of safety and efficacy. We have found the primary endpoint of TLR in 6% of the population with a high variability between in-stent restenosis patients and de novo lesions. Like for PCB, Paclitaxel-coated balloons in-stent restenosis has a higher TLR. Whereas de novo lessions has a very low TLR of 2%. The other endpoints like MACE and bleedings are very low and we are optimistic on the results of this study.

Safety Signals

We have observed no safety signals in terms of bleeding as I was mentioning before, the bleeding rate was very low even because with the DCB technology you may have a very low duration of dual antiplatelet therapy and we have had no thrombotic problems no thrombotic occlusions in our population.

Take-Home Messages

The key take-home message for the clinician regarding EASTBOURNE registry is that, the Sirolimus-coated balloon, this type of Sirolimus-coated balloon is already here showing a very good safety and efficacy profile. So we may want to use these in a real world population. Like the one that has been a role in EASTBOURNE. This is a real world population a lot of calcified lesions, very long lesions. So we can be safe to use this device in this setting.

Next Steps

The next steps are already here because we are running two randomised clinical trials. TRANSFORM I is evaluating this device versus Paclitaxel-coated balloon and TRANSFORM II study is another randomised clinical trial international, which is comparing Magic Touch versus Xience in multivessel diseases. So in the next two years we will have more data on this device.