- Good morning. My name is Alfonso Ielasi I'm an Interventional Cardiologist working at Instituto Clinico Sant'Ambrogio Gruppo Ospedaliero San Donato, Milan Italy. And today I will talk about the results of the Hyper Study.

Study Rationale

Stent length is known to independently predict Restenosis and Stent Thrombosis. Based on this, it is reasonable to consider alternative strategy to manage Diffuse Coronary Artery Disease in order to limit stent length. So the use of a hybrid approach combining DES implantation and DCB inflation in diffuse disease could be an option in this kind of patients.

Hybrid Strategy With DES/DCB

So the definition of the Hybrid Strategy used in our study was as overlapping or slightly super imposing DES, new generation DES implantation in the proximal, more larger part of the vessel or at the main branch of a bifurcation. And when I talk about more larger, I mean segments with a reference vessel diameter superior than 2.75 mm. While the DCB target segment is located in the distal part of the vessel or at the side branch of a bifurcation with an LVD between 2 and 2.75 mm.

Study Design, Selection Criteria and Outcome Measures

So Hyper was a multicenter single arm pilot study. It was conducted in five Italian centres and the primary endpoint of the study was to assess the clinical outcome at one year. Primary endpoint was a device oriented composite endpoint of Cardiac Death, Target Vessel MI and Ischemia Driven TLR in the DES or DCB treated segments.

Key Findings

The one year DOC was 3.7% only related to the occurrence of ischemia driven TLR, which was 3.7%. The events were mostly related to TLR at the DCB target segments. No thrombosis were reported in both the DES or DCB target segments. So this study demonstrated the feasibility and effectiveness of this hybrid approach for the management of diffuse coronary artery disease.

Which Patients Would Benefit from the Hybrid Strategy

Well, each patient with diffuse coronary artery disease, and when I talk about diffuse coronary artery disease, I mean long lesions with lesion length more than 28 mm and bifurcation with an extension of the disease on the side branches of more than 10 mm. As I was saying before the DES target segment is located in the proximal, more larger part of the vessel. And when I talk about more larger, I mean with an reference vessel diameter superior than 2.75 mm while the DCB target segment is located in the distal part of the vessel or at the side branch of a bifurcation with a smaller reference vessel diameter. And when I talk about smaller, I mean between 2 and 2.75 mm.

Next Steps

So the next step will be to focus the use of this strategy for the treatment of very long lesions. So the HYPER-2 Study is ongoing, this is a multicenter international prospective registries where more than 500 patients will be enrolled in order to assess the clinical results following the use of this Hybrid approach for the treatment of very long lesions. And then in case of positive results in terms of visibility and safety, we will move to a direct head to head comparison versus a full metal jacket procedure with DES only. So DES only versus a hybrid approach.