My name is Giulio Stefanini. I'm an interventional cardiologist working at Humanitas Research Hospital in Milan, Italy.

1. What is the POEM Study and what does it aim to address?

The POEM study is a prospective single arm study, aiming at addressing the safety of the synergy bioresorbable polymer-coated, everolimus-eluting stent followed by one month of dual antiplatelet therapy in patients at high bleeding risk.

2. Describe the design, patient population and endpoints?

Mainly to address this aim, what we did was to recruit prospectively patients at high bleeding risk with coronary artery disease who presented at several Italian centres, actually nine centres, to undergo PCI and they underwent PCI with the implantation of a synergy everolimus-eluting stent. And after the PCI the patients were recruited and discharged with an antithrombotic strategy based on the concept of a short DAPT of one month only. To be recruited, patients had to be at high bleeding risk meaning that they had to... have at least one high bleeding risk criteria. And the antithrombotic strategy was based on, as I said, one month DAPT. In patients needing for oral anticoagulation, well, these patients had the antithrombotic strategy based on a P2Y12 inhibitor plus the oral anticoagulation for one month and beyond the first month they continued with oral anticoagulation or only dropping the P2Y12 inhibitor. Well as patients who did not require oral anticoagulation, well those underwent a one month DAPT based on aspirin and a P2Y12 inhibitor. After the first month they dropped the P2Y12 inhibitor continuing on aspirin only. Patients were followed up to one year. The primary endpoint was the composite of cardiac death, myocardial infarction or definite/probable stent thrombosis at one year. And the study was powered for non-inferiority compared with an objective performance criteria derived by the available safety outcomes of the polymer-free biolimus-eluting stents, the Leaders Free Trial.

3. What are the key findings?

The study was prematurely interrupted after the inclusion of 443 patients mainly due to slow recruitment. The patients included were at high bleeding risk but also high ischemic risk if you look at the baseline risk profile. With respect to the antithrombotic strategy the compliance with the discharge therapy was very high so we truly are talking about a high bleeding risk population discharged with one month DAPT, who actually underwent only one month of dual antiplatelet therapy. And with respect to the primary endpoint at one year, we, so the composite of cardiac death, MI, or definite/probable stent thrombosis this occurred in 4.8% of patients at one year mainly demonstrating the non-inferiority which was the primary hypothesis of the study with a P for non-inferiority below 0.001. Since the study was prematurely interrupted so with lower than planned number of patients we performed a post-hoc power calculation, which showed that despite having recruited a lower number of patients we still have a statistical power above 90% to show our primary hypothesis. Looking at the secondary outcomes so mainly ischemic and bleeding outcomes. Actually, the rates were very favourable, very low in this patient population. So, we can conclude mainly saying based on this evidence that in HBR patients, high bleeding risk patients undergoing PCI with a synergy everolimus-eluting stent and undergoing one month DAPT. Well, the study showed non-inferior ischemic outcomes of this strategy as compared with a pre-specified directive performance criteria. And also we showed very low rates of ischemic and bleeding events in this study and therefore very reassuring regarding the application of a one month dual antiplatelet therapy in high bleeding risk patients, in patients treated with this device.

4. What conclusions can be made and what are the implications on practice?

The key conclusions of the study are that, in HBR patients undergoing PCI with the synergy bioabsorbable polymer-coated everolimus-eluting stent, a one month dual antiplatelet therapy regimen resulted in non-inferior ischemic outcomes as compared to specified objective performance criteria and very low rates of ischemic and bleeding events. The implications for clinical practise are that we can safely use the synergy device in HBR patients requiring a very short DAPT. So we start having evidence of a number of devices. We started with the biolimus-eluting polymer-free stent, the biofreedom in the Leader Free Trial. Then this was extended to the resolute Onyx in the Onyx one study, which was showed non-inferior to the biofreedom in the Onyx one trial. And now we also have evidence on the synergy everolimus-eluting stent, which again, was showed non-inferior to the objective performance criteria based on Leaders Free Trial. So we start having sufficient evidence to inform us that we can use safely the synergy everolimus-eluting stent in HBR patients requiring one month dual antiplatelet therapy.

5. What are the next steps?

The next steps, well that's I think it's a very interesting question. On my point of view, the next step would be to evaluate different antiplatelet regimens in these patients, mainly an extended monotherapy which could start already earlier than one month or which could be based on a P2Y12 inhibitor only instead of aspirin, since our patients after the first month, discontinued the P2Y12 inhibitor continuing instead on aspirin monotherapy. What I think is that it could be interesting in this HBR population to evaluate the, let's say chronic secondary prevention strategy with a P2Y12 inhibitor only particularly after the publication of the host exam, just last week in the Lancet in the occasion of the ACC scientific meetings which indeed suggested that there might be an advantage with such strategy instead of aspirin alone.