**Title:**

**Participants: Dr Jose De La Torre Hernandez**

**Date:**

**Dr Jose De La Torre Hernandez**

" - Hello, my name is Jose De La Torre Hernandez. I am the responsible chief of the Internal and Cardiology Department in the Hospital Universitario Marque de Valdecilla in Santander in Spain.

Rationale of the study

The rationale for the OPTIMAL trial is very clear because the LM PCI is a procedure that is becoming very common after trials demonstrating that it's equivalent to CABG in terms of long-term outcomes, that LM PCI should be done with head quality, given the relevance of the location of this disease. Then there is a possibility of using only angiography for the guidance of the procedure or relying on intravascular imaging, particularly intravascular ultrasound imaging. There are registries, mostly registries and very small trials, only two very small trials, comparing angio guidance versus IVUS guidance and all of them consistently suggest a benefit in favour of IVUS guidance in terms of cardiac death, MI, thrombosis, et cetera. But there is not really, is lacking definitely a relevant trial, properly sized, well designed, and that is the reason why we are running with the OPTIMAL trial.

Patient population, enrolment status and study design

This is a randomised trial with a target of 800 patients to be randomised to IVUS guidance versus angio-guidance and these patients are over 18 years old. They have left main disease with indication for revascularization based on ischemia or even in basic examination with, for example, pressure wire and the PCI procedure is considered appropriate by the heart team positioned in the institution. Then these patients that have a clear and well-established indication for LM PCI are those that we can randomise for the OPTIMAL trial. Of course, we have a set of different exclusion criteria. We cannot randomise patients with non ST-segment MI at the moment of the procedure or patients with previous CABG and other criteria like low expectancy of life that are common to these studies. We have three countries involved: UK, Italy, and Spain, nearly 30 institutions and we are now, this is the criteria and with the flow chart, the procedure is just to schedule the PCI and to follow after the randomization the angio guidance or the IVUS guidance. In case of angiography guidance, you just do the procedure up to your criteria, and in case of IVUS, it's necessary that you perform at least it is mandatory, absolutely mandatory, a final IVUS of the stenting of the left main. If only one stent you can do is mandatory, the IVUS examination of the one single stent, in case of two stents, is mandatory. The IVUS running through the two of the stents implanted and we have established optimization criteria. Several targets that you have to meet in order to consider, there is an optimization of the procedure based on.

Potential Impact

The potential impact is really huge because nowadays the recommendation of IVUS guidance for an LM PCI is as class 2, 2A, which is in favour of the usage but is not definitely encouraging the operators to apply and, in fact, worldwide, the penetration, the use of IVUS guidance for this procedures is not really very high. Maybe in nation countries it's high, it's maybe 80%, but in western countries, in European Union or in United States, this penetration is between 20 and 40% and it's because all over the world, people, the operators, cardiologists, considered there is not enough evidence. Then the impact is that in case of positive results, the recommendation could be upgraded to class 1 and the practical, the use in real practice of IVUS-guidance in LM PCI will increase definitely, which is a great benefit for our patients.

Next Steps

Of course, OPTIMAL, we are close to finish enrollment because we have nearly, not definitely, but nearly 700 patients included, we have to reach the the 800 target and we expect to do so in June, July. Then we have two years of follow-up because the primary outcome is established for two years, but at the same time that we are going, waiting for this, we are going to do a strict follow-up with adequate adjudication of the different outcomes of different events by properly designed committees. We also plan to perform some analysis, of analysis that are going to address aspects. For example, what are the best criteria for optimization? Whether there is a prognostic way that the different criteria we have used? The differential effects, of IVUS guidance according to the lesion location in the main distal ostial and IVUS derived outcome. Then the next steps is finishing enrollment in June, we study in June, maybe July. Then two years follow-up, good follow-up, strict follow-up without losing patients and then prepare the main manuscript and also work on different sub-analyses. I think that OPTIMAL is going to be an important landmark trial, building really the evidence for the use of imaging guidance in complex PCI. In this case, it's for left main, there are other trials, like, for example, like achievement that are addressing the same issue but for other complex lesions like calcified lesions, osteo lesions, other bifurcations, CTOs, et cetera, then it's an important trial that is part of a building that is intended to support and to give strong evidence for intravascular imaging guidance of PCI, particularly in complex settings.”