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1. What was the rationale for the MAGSTEMI Trial?

For the trial is the patients treated with intracoronary devices, they are at a higher risk of device-related events. So, from some years in behind, there was a revolution in theory that if we can use a bioresorbable scaffold that disappears from the coronary artery, we can give support to the artery and treat the disease, and then left the artery without any device. And this will in some time overcome the issues of the current-generation drug-eluting stents, and adverse related events to these devices. So now in clinical, in the practice, there was the polymeric BRS, which disappeared from clinical practice because of thrombotic issues. And now, there are the magnesium based BRS, which was the device that was studied in the MAGSTEMI trial. The rationale of this study was that when the device is gone, disappeared, is bioabsorbed by the artery, by the coronary artery. The artery will restore the vasomotion and the normal physiology of the artery.

2. Please remind us of the study design, patient population and endpoints?

To remember the methodology. The MAGSTEMI trial, the original, the main paper was reported in 2019. So at EuroPCR, we reported a trial update of the two years' outcomes. And it was a randomized clinical trial, open-label trial, that was a multicenter trial that was conducted at 11 centers in Spain. So the primary endpoint of the MAGSTEMI trial at one year was a surrogate endpoint, was not a clinical endpoint, was the vasomotion after the coronary injection of nitroglycerin, at one year follow up. And in EuroPCR, we reported the two years' clinical outcomes. So we also look at the clinical outcomes at one year, and then yearly, up to five years. So we are reporting as this report, primary endpoint or primary objectives, the device-related composite endpoint, which you should remember that it's cardiovascular death, it's target vessel MI and target lesion revascularization. And also, we are analyzing in this report the components of these composite endpoints, and also the stent thrombosis or device thrombosis-related events.

3. What are the key findings of this study at 2 years?

So for, remember also a little bit the results from the main report of the MAGSTEMI trial. In 2019, we reported that in fact, patients treated with magnesium-bioresorbable scaffold has a better vasomotion at one year follow-up. And it means that when we do, did, sorry, the coronary angiogram at one year follow-up and we inject nitroglycerin to these patients intracoronary, they have a huge vasodilation of the coronary artery, so there was a higher rate of vasodilation of the coronary artery, so there was sort of restoration of the physiology of the artery and the vasomotion, when it was compared to the comparative device, which was a sirolimus-eluting stent. Nevertheless, at one year, magnesium-based scaffold were related to a higher rate of device-oriented composite endpoint, mainly because there was a higher rate of target vessel revascularization at one year. So the main observation that we did at two years, which is what we are reporting at EuroPCR, is that at two years, this difference between the stents is mundane. So at two years, there's actually a difference in favor of sirolimus-eluting stents in terms of device-related composite endpoints, because there was a higher rate of DRR during the first year. When we did the landmark analysis, when we analyzed the cases between one year and two years follow-up in this time period, there are no difference between the two devices in terms of device-related composite endpoints, or target vessel revascularization. So actually, we look up to all the events, clinical events that I mentioned before, and there were no difference in any of these clinical endpoints. So, between one year and two years follow-up between these two devices, the magnesium-based BRS and the sirolimus-eluting stents, there were no difference in terms of device composite oriented endpoint, there were no difference in terms of patient-oriented composite endpoints, and there were no difference in any of the components of the composite endpoints. So there was no difference in mortality, there was no difference in any type of MI, and there were no difference in revascularization. When we go to the device composite rate there also were no difference between one and two years. So this is the main findings. We have a higher rate at one year, but we have the same rate during the follow up between one or two years.

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

The conclusion that we can do, what we can get from this trial is that in the overall cohort of the patient in the entire follow-up, at two years, this is the higher rate of device composite endpoints because of the higher rate of target lesion revascularization, in the magnesium-based BRS. When it compares to sirolimus-eluting stents. However, we should highlight that between one year and two years follow-up, there is no signal of difference between these two devices. So these two devices, at least in this small sample size of patients, are comparable, for a clinical point of view.

5. Which patients would benefit from the magnesium-based bioresorbable scaffold? What are the possible risks?

We take into account the device generation that we studied in the MAGSTEMI trial, the potential advantages that the patient could get from this type of the device is the restoration of the coronary physiology. And also if you, if the device is completely bioabsorbed in the first year, then the risk of device-related adverse events, such as target vessel relation to myocardial infarction or device thrombosis, virtually disappears. So you can recover physiology from the artery, and also you can reduce the the rate of events after one year. The risk for the patients or what we found that is potentially a background of this device, is that more or less 20 or 25% of the patients, or more, one out of four patients, could have a target lesion revascularization due to device restenosis. So with this, with the current device of magnesium, we are finding a higher rate of target lesion revascularization because of restenosis, and we have look up in the study of MAGSTEMI trial, and probably the recoil of the device and the collapse of the device is producing this type of events in some patients.

6. What are your take-home messages?

My take-home messages is that correlate with the magnesium-based devices, we can recover or restore the physiology of the vessel. And this was shown in primary endpoint of the MAGSTEMI trial. Unfortunately, we have to acknowledge that there was a higher rate of device-related restenosis, or DRR, at one year. Nevertheless, I still believe that magnesium is a very interesting biomaterial for the stent development, because there was a very low rate of device thrombosis. And there are very interesting preclinical work on the biomaterial of magnesium that it's less thrombogenic when it's compared to polymeric bioresorbable scaffold, or even to current-generation drug-eluting stents. So, the take-home message is that we should move forward this technology, and actually the company that developed this stent, is now studying the next generation of the device in the first month trial. And we believe that with an increase on the radial force of the device, and also in a prolongation of the duration of the device of the bioresorbable life of the device, these disadvantages of higher restenosis rate could be overcome. So it could be an improve in the future for the future innovation and the treatment of patients in the next years.