- My name is Wan Azman Wan Ahmad. I'm presenting on the behalf of the Sirolimus Coated balloon De Novo investigators. I am affiliated with the Malaya medical centre. The data that was studied is a randomised trial of Sirolimus coated vs paclitaxel coated balloon in De Novo coronary artery lesions.

Importance of this study

Paclitaxel-coated balloon is recommended and well-established in the treatment of narrow, or blocked coronary arteries which were previously treated with stents This is called in-stent restenosis. Currently Paclitaxel-coated balloon is gaining acceptance in the new blockage, what we call De Novo coronary disease. However, what is not clear whether there is an alternative drug, a sirolimus drug can be alternative to the Paclitaxel-coated drug. So the advantage of the drug-coated balloon is that we do not leave any foreign implant. So this is a preferred strategy because we avoid inflammatory response to the vessel wall. This is in line with the concept of leaving nothing behind. So we studied the novel sirolimus balloon. This balloon, the drug is about 4 microgram per mm squared, it's crystalline coated and additive is Butylated hydroxy toluene. Yes, persistent vessel concentration of up to 50% of the initial concentration at one month. So we compared this balloon, this balloon with the well-established Paclitaxel coated balloon, the SeQuent® Please NEO 3 microgram per millimetre squared to determine the efficacy and the safety of this balloon.

Study Design and Patient Population

The study, the study coordinator, coordination, the data monitoring and the site monitoring is by InnoRa, Berlin and the study device was given by Braun. There are six sites from Malaysia and we have chosen 70 patients with De Novo lesions were enrolled in this study. 35 patients were assigned to paclitaxel coated balloon and another 35 were assigned to the Sirolimus Coated balloon. There is a clinical follow-up of one month, six months and one year and an angiographic follow-up at six months.

Key Findings

The key finding, main key finding is the late lumen loss at six months. Late lumen loss is the luminal diameter of the artery post-treatment and at six months after the follow-up angiogram. So what we found that in the Sirolimus Coated balloon arm, the late lumen loss is 0.1 millimetre. Standard deviation of 0.32 In the paclitaxel arm, the late lumen loss is 0.01 with a standard deviation of 0.33 mm. So the non inferior imaging should be defined as 0.10 - 3.5 was shown. Another interesting finding that we noted that from this study was the late lumen enlargement. This is what we call positive remodelling. The late lumen enlargement is a phenomenon when we see that the healing of the vessel that takes place and this results in the enlargement of the vessel diameter. This is what we call positive remodelling. So we found this positive remodelling is seen in 58% of the patients in the paclitaxel balloon arm and only about 32% in the Sirolimus coated balloon arm. So p is 0.019 which is statistically significant. So we see that in paclitaxel, a patient treated with paclitaxel, the positive remodelling is much more compared to those patients who receive Sirolimus coated balloon. We were also comparing the clinical events between the two groups, the Sirolimus coated balloon and the paclitaxel balloon. There was no difference in MACE as defined by cardiac death, target lesion revascularization or target vessel myocardial infarction. Also no difference between the two arms.

Impact on Practice

I think it's a very, very important study. As I mentioned earlier, the use of drug coated balloons is in line with the concept of leaving nothing behind. Nowadays in patients with coronary artery disease. The default treatment is by stenting. So as we know that we put a stent, we are caging the artery. So if you're able to do without the stent then we can maintain the normal physiology of the artery. And another advantage that is shown that for any foreign material has a much better long-term outcome in terms of mortality and in terms of stent thrombosis. Also being a potential possibility for the shortening of dual antiplatelet therapy so, without this foreign material inside the vessel wall it leaves options, for patients with coronary artery bypass graft surgery in the future. So, with this finding The use of drug-coated balloons in De Novo coronary arteries Then there will be more people who will be willing or be able to use this, this technology in the treatment of coronary artery disease. And we see in our country, the impact on our country, the paclitaxel coated balloon have increased to 50% in the last, our last NCBD PCI report.

Next Steps

Of course, this study was a small study, 70 patients which was randomised into Sirolimus coated balloon and a paclitaxel coated balloon. So we need a longer followup. And of course we need a confirmatory trial.