- So my name is Mohamed Abdel-Wahab. I'm a professor of interventional cardiology, and I am working as an interventional cardiologist at the Leipzig Heart Centre in Germany. And the study we are discussing or presenting today is the choice-closure study.

Importance of this Study

This study examined two different techniques of large-bore vascular access-site closure during transfemoral TAVI. Procedures requiring large-bore vascular access have increased in the last years in interventional cardiology practice. They include, of course transfemoral TAVI, but also include other procedures, such as mechanical circulatory assist devices and endovascular aortic procedures. And for a large period of time, the options we had were limited. They were mainly based on suture-based techniques. And in the last few years, alternative techniques, depending on, or using plug-based technology, have been introduced. So currently we have a variety of closure techniques based on different device technologies. But randomised comparisons in large randomised studies have been very scarce. And this is why we think the study was necessary and this is why we performed the study.

Study Design and Patient Cohort

So this study, the choice-closure study, included 516 patients under transfemoral TAVI at three German centres. These patients were assessed by our team and they were all deemed suitable for treatment through the transfemoral access route. And they were randomised one-to-one between two closure device techniques. One is what we call the pure plug-based technique, using the so-called MANTA device, and the other group was randomised to what we call a primary suture-based closure technique using a double ProGlide technique complemented by a small plug if necessary. These patients underwent the procedure and then were followed up during the hospital stay and up to 30 days. And the primary endpoint of the study was access-site or access-related, minor and major vascular complications defined according to the VARC-2 definition.

Key Findings

So the key findings was that the primary endpoint of access-site or access-related minor and major vascular complications occurred at a significantly higher rate in the plug-based MANTA group compared to the ProGlide-based, or the suture-based, ProGlide group. So the rate of the primary endpoint was 19.4% in the plug-based group compared to 12.0% in the suture-based group, which was statistically significant at the P value of 0.029. There were some secondary endpoints that we assessed as well. So access-site bleeding events were not significantly different between both groups, but were numerically higher in the plug-based group as well, consistent with the findings we found for the primary endpoint. Device failure was low and not significantly different between both groups, though the mode of treatment of device failure showed some differences. And time to hemostasis, which was also a secondary endpoint, was significantly shorter in the plug-based MANTA group compared to the suture-based ProGlide group.

Impact on Practice

We think these findings are important for several reasons. First, the registry data that we had before this trial, or before the publication of randomised trials, actually showed opposite findings. So the registry data, the observational data, show better outcomes, or less vascular complications, with the plug-based technique. Our findings are showing, actually, the opposite. But they are concordant with the findings of a smaller randomised trial that has recently been published called the MASH trial, performed at two centres in Europe. A study of around 200 patients where the findings were concordant, but they were not statistically significant, probably because of a smaller sample size. So we think the findings of these two randomised trials reflect a real observation. The second important clinical implication of this trial, at least in our practise, is that despite the advantages of this plug-based technique showing a shorter hemostasis time, the more common occurrence of muscular complications has prompted us to use this technique only in selected patients and in bailout situations. So it's not the classical or the default closure technique in our practice anymore. The classical suture-based, double ProGlide technique remains the default technique in our practice because it's associated with less vascular complications as has been documented in this trial. Nevertheless, we think that further investigations would be very important in order to analyse, maybe, how to optimise outcomes with a plug-based device. And again, to assess its usefulness as an important bailout technique in patients where the suture-based technique does not function or even fit.

Next Steps

So the next steps. Of course, this is not the end of the journey. So a lot of other devices are also available and have been introduced into the market. So I think the study highlights the importance of scrutinising and carefully analysing all these closure device technologies and techniques in prospective randomised trials to assess the comparative efficacy. And highlights, again, the limitations of observational data. Another important aspect would be to try and optimise the application technique we have for the available devices. Definitely, the plug-based device is an addition, but defining its exact role, and how to optimise outcomes, and reduce complications, would be also very important to be performed in the near future.