- So my name is Andrea Buono. I am an interventional cardiologist working at Fondazione Poliambulanza in Brescia in Italy. And today I will discuss the results of the ITAL-neo registry, a study assessing the safety and efficacy of the new generation ACURATE neo2 transcatheter aortic valve in the context of TAVI.

Background of This Study

Background of the ITAL-neo registry has to be searched on the available evidence produced so far in literature demonstrating the non-negligible incidence of more than mild paravalvular leak with the use of the early generation ACURATE neo in the context of TAVI. For this reason, the producing company, the Boston scientific, has launched on the market at the end of September, 2020 the new iteration, called ACURATE neo2.

Study Design and Patient Population

The device used in the study is the ACURATE neo2. This valve maintain the key feature of the previous generation valve, but incorporates some engineering refinement such as the presence of a radio pack marker on the delivery system, able to guarantee a more precise implantation, but also the presence of a total outer pericardial skirts which reach the upper crown and with an active technology able to guarantee a more synchronous adaptation to the native annulus, with the potential to reduce the incidence of moderate or greater paravalvular leak.

Study Design and Patient Population

Our study is a retrospective, observational, multi-center, independent registry. We enrolled 900 patients consecutive, affected by severe aortic valve stenosis treated in 13 Italian centers which received both generation device. Of the 900 patients, 680 received the earlier generation device, whereas 220 were treated with the ACURATE neo2 valve. To account for the non-randomized nature of the study, we perform the 1:1 propensity score match in order to have the final results of 205 pairs of patients.

Key Findings

The primary endpoint is the incidence of moderate or greater paravalvular leaks at pre-discharge echocardiographic assessment. Whereas secondary endpoints are technical success, but also some short-term clinical outcome intended as 90 days safety, 90 days efficacy, and a single component of the pre-specified composite endpoint. All the endpoints were assessed according to the model BARC three criteria. We demonstrate a significant reduction of the primary endpoint with the use of new generation ACURATE neo2 that occurred in 3.5% of the patients, compare with 11.2% of patients treated with the early generation device. Also the technical success were high in both groups with comparable results. And this is intuitive since this definition does not include the presence of more moderate or greater paravalvular leaks, but also data concerning the short-term clinical outcome are encouraging because we see a higher number of safety and efficacy 90-day success with new generation device.

Take-Home Messages

My take-home message is that ACURATE neo2 is improve its performance especially in the context to reduce paravalvular leak. And I think now this valve is ready to be used in a broad and large population of patients, in the context of TAVI.

Further Study Required

We need randomised controlled trial to confirm our preliminary results.