**Title: EuroPCR 2022: ALIGN-EFS Finds 100% Procedural Success Rate Using JenaValve Trilogy in Pts With AS**

**Participants: Dr Matti Adam**

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**Dr Matti Adam**

- My name is Dr. Matti Adam, I'm from Cologne, University Hospital of Cologne. I live in Germany and I am an Interventional Cardiologist. And today we are speaking about the Trilogy JenaValve System and the data that we presented for patients that we treated with aortic stenosis with the system.

**Aim of This Study**

So the aim of this study was to evaluate the Trilogy JenaValve System, which is a new TAVR system on the market for transfemoral use. And the aim was to evaluate this in patients with aortic stenosis. The system itself got a CE market approval in Europe in the year 2021, very recently, and so we collected data from six German high-volume centres to evaluate this.

**JenaValve TAVR System**

So the special design of that valve is, or the unique design features that this valve has are three locators. And these three locators will go into each layer of each coronary cusp and in each aortic valve cusp and sits there. And once expanded the ceiling ring will get into contact with the locators and basically clip on the aortic valve. So this gives us a little, this gives us certain advantages gives us the advantage of a little, of less dislocation of less dislocation danger. It will give also more seating because this mechanism the slipping mechanism will allow us more seating. And also we have coronary alignment by definition because or by design, because these three locations will go into each cusp and then therefore are aligned. So we were very, yeah, very, very intrigued about the first results of this system.

**Study Design and Patient Population**

So the patient population... So the study design, let's start with that first, was registry after CE mark in 2021. We collected data from all-comer patients, basically who were assigned to get JenaValve for aortic stenosis. So we were looking at aortic stenosis cases in Germany after CE mark in registry in six high volume centres. Overall 73 patients were implanted a JenaValve and 28 of them were patients with aortic stenosis. You'll also have the possibility to see the AR data which is also presented in Paris by Alexander Tamm from Meinz. And I specifically looked at the AS data. It was an intermediate risk population group, so we had a Euro score of 5.9 and it was a very clear aortic stenosis group as well because the mean gradient over the aortic valve was 42.5 and the Agatston score was over 3000, so was highly-calcified patients with the, you know clearly severe aortic valve stenosis.

**Key Findings**

Well, the key findings were that all procedures were done successfully via the transfemoral approach, which was important because the system has been on the market as a transapical system for a couple of years, and now the company has come back with the transfemoral system, the Trilogy System. So of course, I mean, that was an important point that all of the transfemoral procedures were done successfully. There was no conversion through surgery so no second valve implanted, so a highly efficient implantation of one valve with no complications here. We had no major or life-threatening vascular or major bleeding events in our patient population. We had one stroke in that population which was a minor stroke and patient left the hospital without with full with no symptoms left. And there was one death of a patient which was absolutely unrelated to the procedure. It was a patient who was on extracorporeal life support before running into the procedure and ended up, yeah, ended up not surviving because of ischemic brain injury. The performance of the valves itself was outstanding. The reduction of the gradient was down to 6.4 means so very good single digit numbers in terms of mean gradient with the aortic valve area, after development implementation of 2.2. We had no moderate or severe PVL. So, very good results with respect to PVL as well 14% of the patients had mild PVL and 86% of the patients had trace or none. What for me, the most outstanding, the most outstanding part of the data is that we had no pacemaker implantation. So our pacemaker rate was zero percent. So out of the 78 patients implanted with the valve no patient had to be implanted a permanent pacemaker.

**Take-Home Messages**

So the take-home messages for clinicians regarding this registry, I think are that the Trilogy JenaValve system has shown promising results in that early experience with that new system. We had no pacemaker rates after implantation of 28 patients. We had no moderate or severe PVL in these patients. And overall, we had a technical success rate of 100% and a device success rate VARC-3 of 96.4%. So that's quite promising. Also, I think, you know, speaking about lifetime management we have coronary alignment by design with this valve and we will have good coronary access later on. So if you think about that, that might actually be something that we should also consider when we use this valve.

**Next Steps**

Clearly the next steps are to increase numbers. So we will further help setting up a registry of all patients that have been perfectly, that will be the, the aim would be to include all patients and registries that are implanted with the Trilogy System valve. And we have to, of course, wait for data from randomised trials. There are randomised trials in the U.S. and Europe using that system for our Aortic Regurgitation which I think is important. So we might be able to learn something there as well. And also, I mean this, yeah, we need randomised trials for aortic stenosis as well with this valve, and see if the very promising results hold what they promise right now.