**Title: TCT 24: 5 Trials That Will Change My Practice with Dr Mirvat Alasnag**

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**Dr Mirvat Alasnag**

Hello everyone. My name is Mirvat Alasnag, and I'm an interventional cardiologist in Jeddah, Saudi Arabia. And I'm here in Washington DC for TCT 2024.

There have been a good number of late-breaking clinical trials this year, both in the coronary space and the structural space. In the structural space, there is a lot of focus on aortic stenosis and early replacement trials that have been actually very much anticipated by the community.

**EARLY-TAVR**

The first one is the EARLY-TAVR trial that really looked at patients with severe aortic stenosis and were asymptomatic at enrollment. Now, these patients—about 900 patients—were randomized to a watchful waiting strategy versus early replacement. And of course, they tried to trigger symptoms using exercise treadmill tests on these patients. The primary endpoint, a composite of all-cause death, strokes, and unplanned hospitalizations for cardiovascular causes, was actually much lower in the early replacement arm compared with clinical surveillance, occurring at 45.3% in the surveillance compared with 26.8% in those who got early replacement. So it's actually a very promising trial.

Some of the other trials that were actually presented here that looked at early intervention for severe aortic stenosis were not as positive, but nevertheless, we learned from them.

**EVOLVED**

One of them was the EVOLVED trial that looked at 224 patients who had severe aortic stenosis but also underwent cardiac magnetic resonance imaging to look at fibrosis, and they quantified the fibrosis and then randomized these patients to either early replacement compared with watchful waiting again. And, unfortunately, the total number of patients enrolled was about 224—100 plus, 110 plus in each arm. But this was a negative trial. Nevertheless, I think it still means we need to intensify medical therapy, perhaps understand the role of intracoronary—sorry—of imaging to stratify these patients and maybe assess patients with low flow, low gradient aortic stenosis.

**TAVR-UNLOAD**

The last trial was less a trial on aortic valve replacement and more a heart failure trial. This was the TAVR-UNLOAD study that was done. Initially, they had wanted to enroll over 300 patients, but they actually ended up with less than 200 patients—about 150 patients. And they randomized these patients with low ejection fraction and moderate aortic stenosis to either watchful waiting and optimization of guideline-directed medical therapy versus early replacement. And again, it did not meet the significance for the primary endpoint. Now remember, it took a long time to recruit the patients, they ended up terminating it early. So it was really underpowered to give them the information that they actually needed. And guideline-directed medical therapy, when this trial was initially started and designed, was very different than what it is today with the four pillars. So I'm just wondering if a trial like this is done again and given the chance to go to completion, would there actually be a difference? It's something for us to look at.

**ECLIPSE**

And now moving on to the coronary space, an interesting trial that again was much anticipated is the ECLIPSE trial that looked at patients with intracoronary—sorry, with coronary calcification and were managed with modification using orbital atherectomy compared with balloon angioplasty. And they did use optical coherence tomography, and the endpoints for this trial was actually looking at target vessel failure at 1 year and looking at minimum stent area with OCT. And about 2000 patients were included in this trial. Orbital atherectomy and balloon angioplasty alone had very similar target vessel failure and MSA reported at the end of the trial.

Why was it negative? Well, perhaps you know, the role of intracoronary imaging here was done after the fact. And so initially they recruited patients based on fluoroscopy. So I'm just wondering if these patients, in fact, as Gary Mintz mentioned during the TCT meeting and during the discussions, that perhaps these patients—if we had done intracoronary imaging—would not have warranted atherectomy because it's deep calcium and not superficial calcium that needs modification again. So probably, changes in the design of this trial, looking at longer-term outcomes, but you know, looking at the results of orbital atherectomy, that should not impact other modification tools such as rotablation and shockwave lithotripsy. But none of the trials that we have at the moment look at head-to-head comparisons between them.

As an interventional cardiologist, for me, perhaps the endpoint should not be really just looking at target vessels failure, but actually immediate success. I don't think any interventional cardiologist will be implanting a stent in a lesion that is yet to yield and hasn't yielded to balloon angioplasty.

So, you know, without boring you, the other trials that were presented in the coronary space really focused a lot on physiology. So looking at pullback gradients presented by Carlos Collette post-PCI was very intriguing, and looking at some of the others that looked at multivessel PCI guided by intracoronary physiology, some of the CMR trials as well. So I think this space, in terms of intracoronary physiology and the trials that are still in the pipeline, are going to be interesting to look at.

**COSMIC-AS**

Some of the trials, such as the COSMIC-AS trial that looked at using physiology to guide coronary disease in intermediate lesions with patients with AS. Yes, you can use it. So that's a lot of space here that was very useful for us. And I think after the guidelines have upgraded the use of intracoronary physiology, we will probably see a lot more use in clinical practice and hopefully more trials will come in the pipeline.

So thank you and hope to see you another time.