- Hello everybody, my name is Firas Zahr, I'm the director of interventional cardiology at Oregon Health and Science University. It is an honour and privilege to present to you today the 30 day outcomes following transfemoral transseptal transcatheter mitral valve replacement. Intrepid TMVR early feasibility study results.

Reasoning behind Intrepid TMVR

Well, transcatheter mitral valve replacement holds a lot of promise as a new approach for treating mitral valve disease. Historically, we've been dealing with transapical TMVR devices. Those had very good MR reduction. However, there is a lot of safety concern around them. And this trial is a transfemoral mitral valve replacement option with the Intrepid device via a transfemoral transseptal delivery system that is designed to eliminate mitral regurgitation by replacing the mitral valve.

Study design and patient population

So the intrepid transcatheter mitral valve replacement early feasibility is a prospective, multicentral, non-randomized early feasibility study that included 11 centres across the United States. There was clinical and echo outcomes that were designated according to the MRVARC criteria. There was independent physician screening committee, as well as protocol specified echo acquisition that was reviewed by echo core lab and there was an independent adjudication committee for safety concerns and events. The inclusion criteria for the study was patients with at least moderate to severe symptomatic mitral regurgitation who are a high or extreme surgical risk as determined by the local heart teams that incorporate the STS PROM score and they had anatomy that is suitable for the Intrepid TMVR delivery including transfemoral and transseptal access.

Key Findings

So we looked at the first 15 consecutive patients that were approved by the screening committee and at 30-days there was no mortality of this cohort. There was zero stroke, reoperation, or reintervention of the mitral valve and zero new pacemaker implantation. And then there was seven bleeding events in this cohort. Six of them are related to major vascular complication and one was related to GI bleed two weeks after discharge. There was complete resolution of mitral regurgitation with a hundred percent of patients have none or trace mitral regurgitation at 30 days. Also a hundred percent of the patients had none or trace perivalvular mitral regurgitation at 30 days. All patients had mild LVOT obstruction as defined by peak velocity less than three metre per second across the LVOT. One remarkable finding of this study is that the vast majority of have significant improvement in New York heart class association.

Further research

I think this is a early feasibility study with the first-generation 35 French device. The new advancement in the field would lead to development of a 20-29 French device that is under development. And we are hoping that we will have more patients and longer follow-up to validate this encouraging finding of this early feasibility study.