My name is Uri Landes. I am a cardiologist at Rabin Medical Center in Israel.

1. What was the rationale behind this study?

We know that inaccurate implantation of the transcatheter valve during TAVI can happen and may present as malposition or migration/embolisation of the transcatheter valve. And when this situation occur there are several bail-out strategies the operator can act upon. So in early or milder stages or cases some valves have recapturable features and the operators may have a second chance to implant the valve. But many times it is simply too late or the valves does not have recoverable features. Then the most common thing operators do from time to time is urgently implanting a supplementary valve in a better position, either inside the first valve or in a different place If the first one was implanted at ectopic location and currently that's on the sequela or consequences or even the risk factors for these urgent TAVI implantation is very scarce.

2. What was the design, patient population and endpoints?

So this was really a substudy of the Redo-TAVI global registry that we initiated and designed to collect data on patients undergoing redo-TAVI for transcatheter valve dysfunction, for whatever reason. And currently this registry includes 40 centres from Europe, North America, and Israel. But for this analysis, we collected data on consecutive patients that underwent dual valve TAVI from 16 out of these 40 participating centres while defining dual-valve TAVI as attempted implementation of supplementary valve implantation during the single procedure that is the index native aortic valve TAVI procedure. And the principle endpoints were straightforward defined as mortality at 30 days and one year.

3. What are your key findings to date?

So we have a few, first, we noticed that the incidents of procedures in which urgent implantation of the second valve was needed declined over time from 3% in 2014, to 0.9% in 2018. So this was reassuring and nice to see. And then we identified six factors that were independently associated with urgent second valve implantation. So these were a bicuspid aortic valve If the patient had one, a significant aortic valve insufficiency at baseline, arterial fibrillation, alternative TAVI access utilisation also the use of early generation valve and finally the use of self expendable valve. And next, we found that 80% of these cases the indication or the incentive to implant the second valve was residual aortic valve insufficiency after incorrect positioning of the first valve which was 45% too high and 35% too low. The failure of the first valve presented as power valve leakage in most cases.

4. What conclusions can be made and how should this impact practice?

Well, before making any conclusions, we should acknowledge that there are several limitations to this study. First, it is observational and didn't have any independent adjudication of event or core-lab analysis. Also, we used propensity score matching which is well accepted methodology, but can not account for unmeasured bias that are probably also important like anatomical characteristics that we didn't have data on. And also we didn't have data on alternative management strategies which may be important or relevant such as urgent surgery, at least in some patients and we didn't capture these data. Having said that, we can definitely conclude that there are clear temporal trends towards low incidents and less need for urgent implementation of an extra valve during TAVI which obviously outlines the advances entirely over the years, but also, and then being a bit more careful here as some unmeasured bias may still interfere. But it seems that patients with bicuspid aortic valve or aortic valve insufficiency at baseline maybe at increased risk for this complication. There's also our patients in whom the TAVI is done using an alternative access or early generation, and maybe also self expendable valve. And lastly, compare with TAVI with no need for supplemental valve, patient who did need one, It did have a higher burden of complications that indeed translated to higher mortality at 30 day. Not at one year and two years, but early mortality years.

5. What are your take-home messages?

Well, I think we should be very careful when the TAVI valve jumps to the ascending aorta or to the left ventricle. This is not common, but when it does happen we should reassess the options, Is our TAVI population involve more and more low surgical risk patients? So surgery may be one extra option we should think about given the high mortality and urgent TAVI and TAVI strategy. Now I'm not saying it is better and in most situations it is probably not. But we need to keep that option in mind. But more importantly is prevention. Valve malposition should be abolished almost completely if we can. And the procedures obviously should be well-planned and executed. And it seems like we're in a good direction.