- I'm Jag Singh, Professor of Medicine at Harvard Medical School and electrophysiologist at Mass General Hospital.

Could you briefly remind us of the trial’s main aims, design and endpoints?

The clinical trial here is the Solve-CRT trial. This is a trial evaluating LV endocardial casing in patients who were previously untreated with cardiac resynchronization therapy, but are CRT eligible. And the purpose of this particular study, which I'm presenting or just presented is to examine the roll-in patients that is the short-term outcomes in patients who were using Wise-CRT for the first time with no prior implanting experience out here. This was a prospective open-label single-arm multicenter study. The intent was to recruit about 90 patients eligible for this study, and follow them up at one, three and six months. And the endpoints for the study were primarily to look at primary safety endpoints, type one complications, and also the primary efficacy endpoints, which are to examine the mean percent change in the left ventricular end systolic volume and the number of subjects with improvement in left ventricular and systolic volume and diastolic volume and rejection fraction. I think an important part for me to really mention is that the Wise-CRT system, which many people may not be familiar with really is a unique disruptive pacing strategy that involves putting a left ventricular electoral into the LV endocardium transfemorally or transseptally. Along with this, there a subcutaneous implant of an ultrasound transmitter and the ultrasound transmitter sends ultrasonic waves, this is battery powered, to the LV electrode. Endocardially this is converted into electrical energy and paces the heart. So the intent out here was to primarily look at patients who were previously untreated because of either failed CS implants or deactivated leads, and see if they could potentially be enhanced in their outcomes. And at the same time also look at patients who are CRT non-responders in this particular limb of the study.

What were the key findings from phase 1 of the Solve-CRT Study?

So the results obviously were very interesting. We recruited a total of 31 patients as a part of this roll-in phase. And I may not have mentioned this, there were total 19 centres that were implanting the Wise-CRT system for the first time. 15 of them were in the US, three were in Australia, one in the UK. And about half of these patients were women. Half of them were non-ischemic and majority of them were class three NYHA patients. About 48, almost half of the patients were actually CRT non-responders. So they had CRT units and the patient had non-responded to CRT. And another half of patients were either unsuccessful CS lead placements or CS lead was turned off in those patients. And now they were offered Wise-CRT to implant them and offer them resynchronization therapy. The results really showed that the LV endocardial electrode can be safely implanted in all these patients with no deaths and no significant cardiac tamponade or pericardial effusions in any of these patients. So that was a really good finding. There were three type one complications. Type one complications could be complications related to the procedure or the device itself. The main ones, the three ones were, was a superficial infection, which was treated with antibiotics. The second one was I think that was an electrode dislodgement, which was then subsequently appropriately snared and another appropriate LV endocardial electrode was implanted. And the third one was missed or I would say a relatively poor LV capture was seen in one of these patients. With respect to the efficacy end point, again, the results were really good out here. A majority of the patients actually showed an improvement in their rejection fraction and diastolic volume in end systolic volume. And along with this, there was an improvement in their heart failure symptoms, primarily an improvement in their NYHA class, as well as their KCC2 scores. So overall the results really looked great.

How should these findings impact practice? What are the next steps?

Yeah, so these findings really, I think, create the platform for completing the Solve-CRT study. So around the COVID-19 pandemic, the Solve-CRT study, which was primarily initially a multi-center randomised prospective study has now become a single arm, a multicenter prospective open-label study. So it's now looking primarily at an addition number of patients to really confirm the same primary safety and efficacy end points that we saw with the roll-in patients. We hope to finish recruiting all the patients for this study within the coming next year. And hopefully should have the results for the next conference.