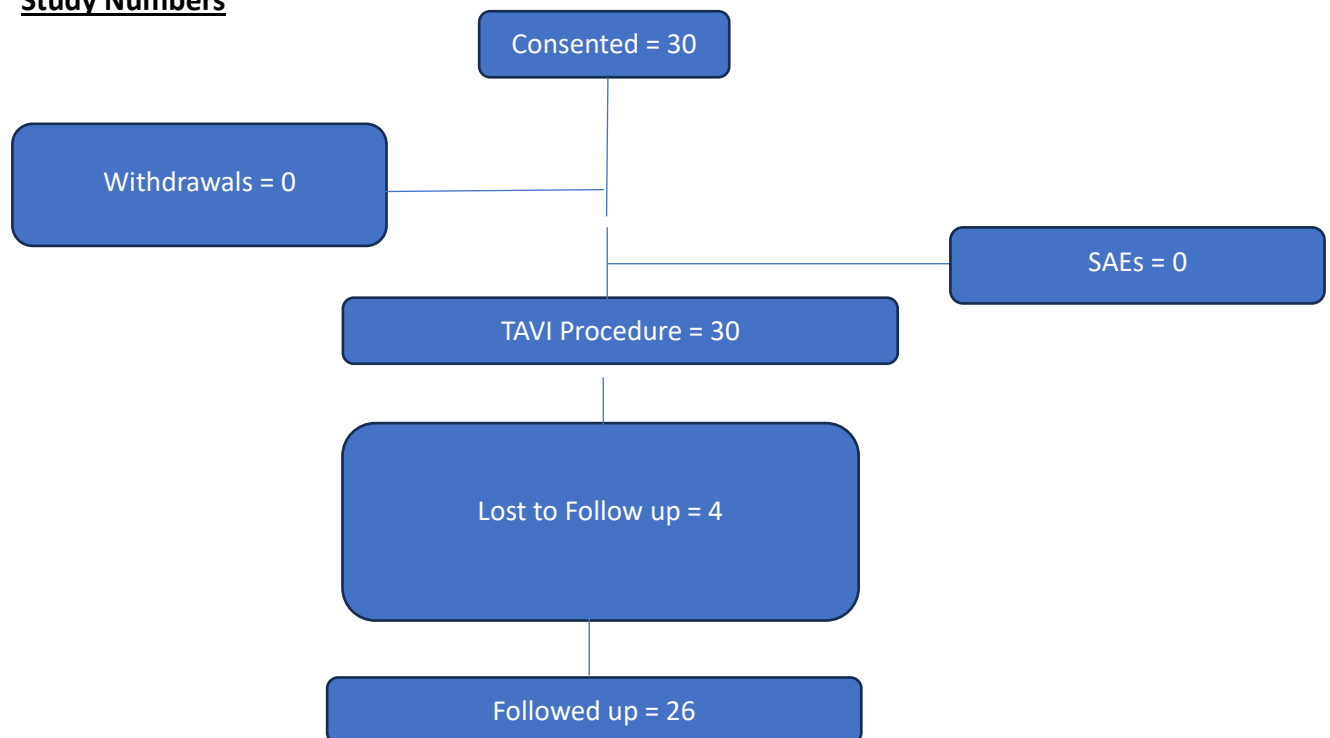


Technical feasibility of neo-commissural alignment in Transcatheter Aortic Valve Implantation (TAVI): an exploratory study in patients undergoing TAVI describing procedural outcomes and effect on coronary artery access (NeoTAVI)

Results

Trial registration number: ISRCTN16090439

Study Numbers



Demographics

	Number	Percentage
Male	17	56.7
Female	13	43.3
Age range	73-91	

Baseline Characteristics

	(n=30)
	Co-morbidities
Previous cardiac surgery	6 (20%)
peripheral vascular disease	1 (3%)
hypercholesterolaemia	21 (70%)
Liver disease	0 (0%)
pulmonary disease	6 (20%)
Pre-procedure pacemaker	4 (13%)

Outcome Measures

	N = 26
TAVI valve alignment compared to patient's own aortic valve measured using cardiac-CT focusing on calculating the optimum commissural alignment during surgery	24 (92%)
Coronary access using standard diagnostic catheters measured using CT-fractional flow reserve before and after the TAVI procedure	24 (92%)

Title

Technical feasibility of neo-commissural alignment in Transcatheter Aortic Valve Implantation (TAVI): an exploratory study in patients undergoing TAVI describing procedural outcomes and effect on coronary artery access (NeoTAVI)

Introduction

The NEO TAVI study was an interventional study conducted at the Royal Sussex County Hospital, Brighton, UK. The chief investigator was Dr Chris Pavitt and the sponsor was University Hospitals Sussex NHS Foundation Trust. Terumo Medical funded the study through an educational grant but they were not involved in the study design or data analysis. There were no competing interests for any of the investigators.

Background and study aims

Aortic valve stenosis is a type of heart valve disease in which the valve between the lower left heart chamber and the body's main artery (aorta) is narrowed and doesn't open fully. This reduces blood flow from the heart to the aorta and to the rest of the body. If symptoms become severe it is necessary to replace the valve. A minimally invasive way of replacing a heart valve is through what is known as a transcatheter aortic valve implantation (TAVI) procedure. Currently, during a TAVI procedure, the new valve is not placed in the exact orientation of the old valve because a technique for doing this routinely has not been developed and, also, it has not been proved if orientation of the valve is important..

During surgical (not TAVI) replacement of a heart valve, which is more invasive, the new valve is placed in the same orientation as the old valve, because it is postulated that it may help blood flow and that orientating the valve in this way will make it easier to access the heart arteries if it is needed in future for any reason, such as implanting a stent to treat a heart attack. We know from previous studies that it takes longer to open a heart artery if you have had a TAVI.

The aim of this study is to try and see if the new valve can be put in the exact orientation as the old valve and if this will have an effect on how the valve functions or changes blood flow through the heart arteries.

Study design

The study design was reviewed by the sponsor's Pre Sponsorship Review Panel which includes members of the public. It involved inviting patients undergoing TAVI at the Royal Sussex County Hospital over a one-year period (September 2022 to September 2023) to take part in NeoTAVI. Those involved had their new valve implanted in the same orientation as their own diseased valve using imaging from CT scans (a type of three-dimensional X-ray scan) which are routine for planning the procedure. After the new valve was deployed with this intended orientation, the patients' heart arteries were accessed using standard tubes called catheters to see how easy it was to gain access. Patients were then invited back for a repeat, focused CT scan of their new valve to see how accurate we had been in implanting the valve in the desired orientation and whether any part of the new valve was partially blocking access to the heart arteries.

Results

30 patients (13 Female, 17 Male, age range 73-91) agreed to take part in the study and our results demonstrate that the technique we developed to achieve valve alignment was efficient. In 92% of

cases the valve was aligned either perfectly or with mild mis-alignment (which is clinically acceptable) and only in one instance was the valve significantly mis-aligned. Access to the coronary arteries was achievable in almost all cases and only in 2 instances were we unable to access the artery (on one occasion the artery was blocked, which was not known prior). We also demonstrated an important additional finding that the valve type used may influence coronary access more than the alignment per se, though the number of patients in this study was too small to draw definitive conclusions.

Patients were asked at the time of enrolment if they would wish to have a copy of the results sent to them and the results of the study have been presented at an international conference (European Society of Cardiology 2024, London). A full manuscript is being prepared for publication.

Summary

In summary we have shown that by using CT imaging, a replacement valve can be positioned with the same orientation as the patient's own valve in the majority of cases with a positive impact on accessing the heart arteries. This is important for patients in the future if a heart artery stent was needed. Theoretically, aligning the valve in this way makes it easier to replace with another TAVI valve in the future and this area needs further research.

The chief investigator, study team and sponsor would all like to thank the trial participants for making this study possible.

This lay results summary has been reviewed by the UHSussex Research Champions, including members of the public, patients and patient representatives