A pilot study on the cause of recurring cerebral thrombo-embolic events after Branched Thoracic Endovascular Aneurysm Repair

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This is a pilot study for investigating the cause of recurring cerebral thrombo-embolic events in a patient after (branched) TEVAR surgery. The main aim of this logistical pilot is to develop a workflow for investigating blood flow patterns in such…

Ethical review	Approved WMO
Status	Pending
Health condition type	Other condition
Study type	Observational non invasive

Summary

ID

NL-OMON57443

Source
ToetsingOnline

Brief title
bTEVAR stroke

Condition

- Other condition
- Vascular therapeutic procedures
- Embolism and thrombosis

Synonym
cerebral thrombo-embolism, stroke

Health condition

aneurysmata

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit Twente
Source(s) of monetary or material Support: Terumo Aortic,Top Technology Twente; een collaborative research agreement tussen Terumo Aortic (Inchinnan;UK) en de Universiteit Twente (Connecting Industries Call agreement (November 2022). Het onderzoek is deel van het promotietraject van de coördinerend onderzoeker.

Intervention

Keyword: - Blood flow imaging, - Branched thoracic endovascular aneurysm repair, - Cerebral thrombo-embolic event

Outcome measures

Primary outcome

This study will yield a workflow for investigating blood flow in carotid arteries and stented aortic arch region of a patient who suffered from recurring thrombo-embolic events after stentgraft placement (bTEVAR) using two imaging techniques. Blood flow will be investigated using 4D-flow MRI and blood Speckle tracking. Flow boundary conditions in the carotid arteries (blood Speckle Tracking) and aortic arch, including branched arteries such as subclavian arteries, common carotid artery and visceral branch vessels (4D-flow MRI) will be investigated. This will be analysed in the form of volumetric flow rates and velocity fields, besides the regular anatomical scans. Other quantitative parameters, such as wall shear stress and residence time, will be investigated as well.

Secondary outcome

Stentgraft deformation over the cardiac cycle will be analysed from ECG-gated CT scans using an in-house Python algorithm. These parameters will be related

to the observed flow patterns. The patient's history of strokes after bTEVAR will be used to draw any conclusions on certain flow or stentgraft deformation patterns that might have caused these complications to occur.

Using the algorithm mentioned above, it is also possible to segment the stentgrafts from the CT scans. In the future, these segmentations will be used for futher in-vitro and in-silico modelling of this patient case. Heart rate and systolic and diastolic blood pressure measured during the ECG-gated CT scan session at the hospital will be retrospectively recorded. Together with paramteters extracted from the 'cardiac' MRI, this will help tune any flow models when mimicking this patient-specific case in physical or digital models.

Study description

Background summary

With high rates of stroke after fenestrated or branched TEVAR, it is crucial to investigate the cause of cerebral thrombo-embolic events to reduce the risk of complications after TEVAR surgery. It has been hypothesised that deformation of stentgrafts occurs by stentgraft rings moving closer together, which causes the fabric in between the rings to fold inwards (concertina-effect). Regions of reduced or stagnating blood flow - causing red blood cells to remain at certain locations with a higher residence time - and increased fluid shear stress could occur in the folds. These two hemodynamic changes combined will promote platelet activation, which could contribute to thrombus formation in stentgraft limbs. However, the relation between these blood flow patterns, stentgraft deformation patterns and stroke rates after a (branched)TEVAR treatment still remains unknown.

The first step towards understanding strokes after bTEVAR is to investigate blood flow patterns in patients who suffered from such complications after implantation of a Relay ® Branch stentgraft (Terumo Aortic, Vascutec Ltd, Inchinnan, UK). The patient population that fits this description is relatively small and we are still uncertain about whether the blood flow patterns can be

measured in these patients, along with the quantification of the parameters we are interested in. That is why a logistical pilot will be performed on one patient. The aim of this pilot is to develop a workflow for investigating blood flow in the aortic arch and carotid arteries of such a patient using two imaging modalities. With this, we can investigate if it is possible to measure the parameters that we hypothesize- in combination with clinical outcome - are able to give crucial information about which flow patterns are deemed favourable or unfavourable regarding the formation of thrombus and thrombo-embolic events.

The blood flow patterns will be investigated using two different imaging modalities. The first method is phase-contrasted four-dimensional magnetic resonance imaging (4D-flow MRI), to be applied to image broad blood flow direction and velocity in the aortic arch and branches. The second method is using blood Speckle Tracking (bST), a high frame-rate echography technique used to image high resolution blood flow patterns, to be applied in the carotid arteries. Blood flow will be investigated using parameters such as stagnating or recirculation blood flow patterns, flow velocity and wall shear stress. Hypothetically, certain unfavourable flow patterns in the aortic arch and/or the carotid arteries will be observed in the patient who suffered complications. In the future , these patterns can be compared to those in healthy volunteers to gain insights into which blood flow patterns could contribute to thrombo-embolic events after (b)TEVAR.

This data collection will lead to a broader *Stented Vascular Triplet* project, in which besides analysing the in-vivo scans, in-vitro (physical phantom fabrication) and in-silico modelling (computational fluid dynamics) will be performed. These models and additional imaging experiments will give even more detailed flow and stentgraft deformation information. This will aid understanding and prevention of complications after (branched)TEVAR surgery by for example optimising stentgraft design in the future.

Study objective

This is a pilot study for investigating the cause of recurring cerebral thrombo-embolic events in a patient after (branched) TEVAR surgery. The main aim of this logistical pilot is to develop a workflow for investigating blood flow patterns in such a patient using two imaging modalities. With this, we can investigate if it is possible to measure the parameters that we hypothesize- in combination with clinical outcome - are able to give crucial information about which flow patterns are deemed favourable or unfavourable regarding the formation of thrombus and thrombo-embolic events.

Blood flow patterns - a combination of anatomy, blood flow velocity, direction - and quantitative parameters such as wall shear stress in the stented region of the aorta and carotid arteries leading to the brain using 4D-flow MRI and blood Speckle Tracking. Comparison of results to those of healthy volunteers in

the future will gain insights into which of the observed patterns contribute to thrombus formation after bTEVAR.

Study design

This observational study will be performed in one patient from the Medisch Spectrum Twente (MST) hospital in Enschede, the Netherlands.

Study burden and risks

The present study carries no risks for the participant. Blood Speckle Tracking and 4D-flow MRI are safe diagnostic procedures. The patient included in this study will visit both the University of Twente and the Rijnstate hospital, so it will take up some of their time (both visits will take approximately 1.5 hours)

This research might benefit the patient with complications after bTEVAR to gain insights into why the recurring strokes events occurred, depending on the outcomes. The outcomes will also give rise to more advanced in-vitro or in-silico research in the future.

Contacts

Public
Universiteit Twente

Hallenweg 5
Enschede 7522 NH
NL
Scientific
Universiteit Twente

Hallenweg 5
Enschede 7522 NH
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

Patient with complications after bTEVAR:
- History of thoracic abdominal aneurysm in thoracic branch of aorta, treated by branched TEVAR with a Terumo Aortic Relay ® Branch endoprosthesis in situ.;
- Recurrent cerebral thrombo-embolic events during follow-up after bTEVAR-surgery.;
- Willingness to undergo MRI scans and blood Speckle Tracking measurements.;
- Able to provide informed consent (IC).

Exclusion criteria

- Irregular heartbeat.;
- Depth of carotid artery too large (distance to skin > 3.5 cm)
- The standard MRI exclusion criteria (such as pacemakers, cerebral vascular clips, pregnancy, claustrophobia etc.).

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-04-2025
Enrollment:	1
Type:	Anticipated

Medical products/devices used

Generic name:	Relay ® Branch endoprosthesis. This is a custom-made stentgraft that is implanted to treat an aneury
Registration:	No

Ethics review

Approved WMO Date:	29-04-2025
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL87739.091.25