Aortic Dynamics after Endovascular Aorta Repair

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Gaining information on the dynamics and shape of the stent graft and stented target vessels, and how these change over time will improve our understanding about the fixation and/or sealing of the stent graft, which may help in stent graft selection…

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Aneurysms and artery dissections
Study type	Observational non invasive

Summary

ID

NL-OMON49871

Source
ToetsingOnline

Brief title
ADEAR

Condition

- Aneurysms and artery dissections

Synonym
Aneurysm, Aortic pathologies

Research involving
Human

Sponsors and support

Primary sponsor: Medisch Spectrum Twente
Source(s) of monetary or material Support: Ministerie van OC&W,Terumo,unrestricted grant van Terumo Aortic (fabrikant van de te onderzoeken grafts)

Intervention

Keyword: Expansion, Longitudinal, Pulsatility, Thoracic Aorta Repair

Outcome measures

Primary outcome

To gain insight in the parameters that influence the success and failure of the proximal fixation and/or sealing of Thoraflex Hybrid device and Relay(Branch) stent grafts.

More practically, this leads to the questions of how the diameter of the (proximal) stent rings changes during the cardiac cycle (pulsatility), how the diameter changes over a period of several months (expansion) and how the grafts interact with the dynamics of the stented target vessels.

Secondary outcome

• How does the estimated vessel compliance change during follow-up?

• Can we observe other kinds of motion that change over time?

• What are the differences and similarities of thoracic endograft vs. thoracic hybrid graft (Relay(Branch) vs. Thoraflex Hybrid) considering:

o Expansion?

o Pulsatility?

o Conformability to the native vessel?

Study description

Background summary

Thoracic endovascular aortic repair (TEVAR) is the mainly used treatment for thoracic aorta pathologies (TAP) due to its less invasiveness compared to the conventional open surgical aneurysm repair. *Regular* TEVAR is performed in pathologies of the descending thoracic aorta, but when the aortic arch is included in the pathology hybrid-TEVAR with a frozen elephant trunk (FET) or branched-TEVAR (BTEVAR) may be performed as well. Different types of endografts are developed for different procedures, including personalization options to fit best to the anatomy of each patient. Endografts of interest in the present study are the Relay(Branch) and Thoraflex Hybrid. Once implanted, the aorta dynamics and the device affect each other in ways that are currently not understood. Pre and post-operative imaging of aortic aneurysm is routinely performed using computerised tomographic angiography (CTA). However, these static techniques do not consider the aorta dynamics. Consequently, our understanding of the dynamic behaviour of the stent graft and stented target vessels is limited. Electrocardiogram (ECG)-gated CTA is a technique that takes the patient*s heart cycle into account, enabling studies to the motion of aorta and implanted devices.

Study objective

Gaining information on the dynamics and shape of the stent graft and stented target vessels, and how these change over time will improve our understanding about the fixation and/or sealing of the stent graft, which may help in stent graft selection and in designing stent grafts that are more durable.

Study design

Explorative observational cohort study with patients with an thoracic aorta pathology undergoing repair
with the Thoraflex Hybrid graft (Hybrid-TEVAR) or the Relay(Branch) graft ((B)TEVAR).
Included patients will undergo ECG-gated CTA preoperatively and at set points during follow-up to investigate geometry and dynamic changes over time and during the cardiac cycle.

Study burden and risks

The main risks of patients during follow-up after a TEVAR procedure are, with or without inclusion in this study, the increased radiation exposure due to repeated (ECG-gated) CT scans and the applied contrast fluid. The administration of contrast fluid can be nefrotoxic and will for these ECG-gated CTA's not be applied in case of kidney dysfunction (eGFR <30 ml/min) or allergy.

Clinical guidelines today advice CT scanning for follow-up of patients that underwent (hybrid/B)TEVAR. Therefore, in the next calculations we only consider

the only the extra radiation exposure that an ECG-gated yields in comparison to a regular CT scan. In some institutions ECG-gated CT is even used for default follow-up after hybrid or endovascular treatment of aortic pathologies.

The scan protocol for the ECG-gated CTA scans of the present study is specifically designed for this study with input of the PI, the coordinating investigator, CT technologists and a medical physicist. The radiation dose exposure following an ECG-gated CTA according to this scan protocol was estimated during a phantom test on the SIEMENS Somatom Definition Flash CT scanner at the Medisch Spectrum Twente hospital. An Alderson Phantom (Radiology Support Devices Inc.) was used to estimate the radiation dose for a regular patient. From a practical point of view we maintained the mammae on the phantom, realizing an overestimation of the effective dose (E) for male patients, while the majority of the patients are expected to be male. Two scan trajectories were scanned: the maximal preoperative scan trajectory (vertebrae C3 to vertebrae L2), i.e. an overestimation of the expected average radiation exposure and an average scan trajectory by diaphragmation. The E then varies between 8.9 resp. 10.6 mSv per scan (DLP: 636-758 mGy.cm), resulting in a total extra dose for the 4 scans (1 preoperative, 3 postoperative) of 39 mSv. Pre-operatively the ECG-gated scan will in most cases be extra; postoperative (before discharge, 6-8 weeks postoperative and 12 months postoperative) will be instead of a regular CTA. The regular CTA has an E of ~2.0 mSv (simulated with same test set-up as ECG-gated CTA). In total, a patient would then obtain a (maximal) E of 39 - 3*2.0 = 33.0 mSv extra when participating in this study.

Taking into account the ALARA ("as low as reasonably achievable") principles, several points were made: first, the exact scan trajectory will be set for each individual patient (in practice this would be approximately preoperatively C3-T7 for stent grafts in the aortic arch and C6/7-T12/L1 for stent grafts in the descending aorta; postoperatively the scan trajectory will be 3 cm above and 3 cm below the stent graft). Consequently, the maximal scan trajectory in the calculations above would not be reached. Also, the scan protocol is in a way that the dose will be optimized for each patient: a skinny patient will receive a smaller dose than an obese patient.

Furthermore, the included patients are 65 years and older. Based on the ICRP 62, a correction factor can be used of 1/5 to 1/10 for patients older than 50 when categorizing them into a risk/benefit category. Based on age and average life expectancy of this patient population, a correction factor of 1/7.5 was chosen. The corrected total extra radiation exposure for the patients for this study then would be 33.0/7.5 = 4.4 mSv. This corresponds to risk/benefit category IIb, i.e. the chance of developing a radiation induced cancer for these patients would be of magnitude 1 in 10,000. The level of social benefit schoul be "intermediate to moderate". As was also stated elsewhere, previous studies with ECG-gated CT scans in several endovascular aorta reperations has led to multiple recommendations in the placement of the devices and even alterations in the instructions for use, and thereby improved the treatment

type(s). With the present study we expect this as well.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

• Asymptomatic thoracic aortic pathology
• Age > 65 years
• Indication for aortic pathology treatment according to standard practise
• Anatomically suitability for one of the investigated grafts

Exclusion criteria

No informed consent obtained
eGFR < 30 ml/min
Allergy for intra venous contrast fluid

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	02-11-2020
Enrollment:	40
Type:	Actual

Ethics review

Approved WMO

Date:	26-08-2020
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

ID: 24172
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL72114.091.20