Quantitative monitoring of abdominal aortic aneurysms using intravascular and three-dimensional ultrasound

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Primary Objective:Patient-specific full geometry assessment of abdominal aortic aneurysms (AAA). The assessment includes the shape and thickness of the intraluminal thrombus and the aortic wall.Secondary Objective(s): IVUS-based assessment of tissue...

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

Summary

ID

NL-OMON55326

Source
ToetsingOnline

Brief title
AAA IVUS

Condition

- Aneurysms and artery dissections

Synonym
'AAA', 'abdominal aortic aneurysm'

Research involving
Human

Sponsors and support

Primary sponsor: Catharina-ziekenhuis
Source(s) of monetary or material Support: Eindhoven MedTech Innovation Center (e/MTIC)

Intervention

Keyword: abdominal aortic aneurysm, aorta, IVUS, ultrasound

Outcome measures

Primary outcome

Patient-specific full geometry assessment of abdominal aortic aneurysms (AAA).

The assessment includes the shape and thickness of the intraluminal thrombus

and the aortic wall.

Secondary outcome

IVUS-based assessment of tissue deformation for improved modelling of AAAs.

Global and local characterization of tissue deformation will describe the

elastic behaviour and wall stress of both thrombus and wall. A novel

multi-perspective ultrasound imaging platform, combining high-frequency

intravascular and 3D ultrasound imaging allows for such quantitative functional

imaging.

Patient-specific pressure data, gender and year of birth.

Study description

Background summary

Abdominal aortic aneurysms are the 13th leading cause of death in Western world for people aged between 60 and 85 years. Criteria for intervention (maximum diameter exceeds 5.5 cm in males, 5.0 cm in females, or a growth rate of 0.5 cm in 6 months) have shown to be unreliable[1][2]. Hence, a new approach for rupture risk assessment is needed[3][4]. From a mechanical point of view the aneurysm will rupture if the mechanical stress, induced by the blood pressure, exceeds the local strength of the vessel wall. Therefore, the strength of the vessel wall and the local elastic behaviour of the vessel wall, could be better

predictors for rupture risk[5][6]. In this study, the global and local elastic behaviour of the aneurysmal abdominal aortic wall and thrombus are characterized by the analysis of intravascular and real-time 3D ultrasound images.

The advantage of this study, compared to other studies in the literature, is the use of multi-perspective images obtained by the combination of intravascular ultrasound[7] and non-invasive 3D ultrasound images[8]. Previous research for AAA rupture risk assessment used mainly Computed Tomography (CT)[10] and sporadically Magnetic Resonance Imaging (MRI)[11]. However, due to the radiation exposure, the use of nephrotoxic contrast agents and the lack of temporal resolution, CT cannot be used as a routine screening method for patients with an abdominal aortic aneurysm. MRI has a high soft tissue contrast, however it is expensive and has limitations regarding the resolution. Therefore ultrasound imaging is the ideal image modality since it has a high temporal resolution, the ability for real-time 3D imaging, and the low costs. While nowadays researchers often still assume a uniformly distributed wall thickness of 2 mm of the whole aorta[11], the addition of intravascular ultrasound images will provide the ability to measure the wall thickness locally with high precision. Using intravascular and 3D ultrasound imaging combined, the full geometry, the global distensibility, and local elasticity of the aortic wall and thrombus can be determined[12]. Furthermore, stress analysis can be performed, using the same data as vital input.

Ultimately, this study is intended to accurately assess the rupture risk potential of the aneurysm. This would support screening, diagnosis and clinical decision making in terms of the need of endovascular aneurysm repair.

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Study objective

Primary Objective:
Patient-specific full geometry assessment of abdominal aortic aneurysms (AAA). The assessment includes the shape and thickness of the intraluminal thrombus and the aortic wall.

Secondary Objective(s):
IVUS-based assessment of tissue deformation for improved modelling of AAAs. Global and local characterization of tissue deformation will describe the elastic behaviour and wall stress of both thrombus and wall. A novel multi-perspective ultrasound imaging platform, combining high-frequency intravascular and non-invasive 3D ultrasound imaging allows for such quantitative functional imaging.

Study design

This is a study for patients who will undergo an already scheduled endovascular aneurysm repair (EVAR). When the patient agrees to participate in the study, first, an additional non-invasive 3D ultrasound dataset is acquired of the abdominal aortic aneurysm (AAA). 3D ultrasound is without any risks and takes no additional time. Second, the patient will be prepared for the EVAR. This procedure carries certain risks including damage to the blood vessel, bruising

or bleeding at the puncture side, and infection. These risks are mostly caused from placing the guidewire, which is needed to be done for the EVAR procedure. These risks are already present, and are not caused by the addition of the measurements for this study. Before the stent-graft is actually placed, the already positioned guidewire is used for an additional intravascular ultrasound measurement of the AAA. The catheter will be pulled-back at a speed of 0.5 mm/s using a motorized pullback device. The risks of this intravascular ultrasound are negligible, since these measurements are performed using the same guidewire that is already necessary for the EVAR procedure. Furthermore, this intravascular ultrasound takes maximum 10-15 minutes. Finally, a last non-invasive 3D ultrasound dataset is acquired at the same position. These 3D ultrasound images include the guidewire which is necessary for registration. The intravascular ultrasound measurement automatically obtains both DICOM and envelope data. Envelope data is the post-processed received ultrasound data before it is transformed into DICOM data. This envelope data does not require additional measurements or time and will therefore not influence the procedure. Using the envelope data, the AAA tissue deformation can be measured more accurately and the thrombus can be segmented more accurately.

Multiple patient-specific datasets including both intravascular and 3D ultrasound are necessary to determine the global and local elastic behaviour and aneurysm wall characteristics. A large amount of datasets is required because the use of deep learning techniques in post-processing.

Offline analysis will be performed on the intravascular and 3D ultrasound datasets and consists of post-processing of the data: wall and thrombus segmentation, motion tracking and elastography. Also a novel multi-perspective ultrasound imaging platform, combining high-frequency intravascular ultrasound and 3D ultrasound will be used. Furthermore, a patient-specific Finite Element Model will be used to simulate the elastic behavior and the wall stress based on the multi-perspective imaging data. These methods will be developed using Matlab© and ABAQUS© software and applied to the available data to estimate the elastic behavior mechanical properties of the AAA vessel wall and thrombus in time. This post-processing is performed by the principal investigator, at and in collaboration with, the Eindhoven University of Technology (TU/e). As a secondary user, Philips and affiliates will receive the data for post-processing.

This is a feasibility study in which we are unsure about the percentage of patients of which we can acquire successful measurements. All patients who want to participate in this study are included. The required number of 50 patients is based on the total amount of patients who are scheduled for an endovascular aneurysm repair in the Catharina Hospital Eindhoven, which is about 80 patients every year. Therefore, it would be feasible to include approximately 50 patients in the upcoming two years.

Study burden and risks

There is no personal benefit in taking part in this study. The research adds maximum 10-15 minutes to the total EVAR procedure. The catheter for the intravascular ultrasound will use the guidewire that is already in position for placing the stent-graft during the EVAR procedure. Any procedure that places a catheter inside a blood vessel carries certain risks. These risks include damage to the blood vessel, bruising or bleeding at the puncture side, and infection. These risks are mostly caused from placing the guidewire, which is already done for the EVAR procedure. The risks associated with the extra intravascular ultrasound pullbacks itself can therefore be considered negligible.
In summary, the patients are only asked 10-15 minutes of their time, and in return, they will contribute to an increment in knowledge about the influence of thrombus and the risk assessment which ultimately will replace diameter surveillance, prevent premature rupture of AAAs, prevent overtreatment of AAAs and reduce the risks and costs involved.

Contacts

Public
Catharina-ziekenhuis

Michelangelolaan 2
Eindhoven 5623EJ
NL
Scientific
Catharina-ziekenhuis

Michelangelolaan 2
Eindhoven 5623EJ
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Patients with AAA that undergo an EVAR procedure

Exclusion criteria

Minors, incapacitated adults and mentally incompetent adults will not be included in the study. Subjects that do not want to participate will also not be included.

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Health services research

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	18-05-2022
Enrollment:	29
Type:	Actual

Medical products/devices used

Generic name:	Intravascular ultrasound (IVUS)
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	11-02-2021
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	15-01-2025
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

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	NL75083.100.20