Feasibility of the use of Ultrasound Doppler-derived patient-specific velocity profiles in fluid-structure interaction modelling of the abdominal aorta, femoral artery and carotid artery

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Main goal:The main goal of the study is to show the feasibility of using Doppler US derived patient specific velocity profile in the abdominal aorta, carotid artery and femoral artery, in order to improve the Fluid-Structure-Interaction models of...

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

Summary

ID

NL-OMON53799

Source
ToetsingOnline

Brief title
Feasibility of the use of Ultrasound Doppler to measure velocity profiles

Condition

- Aneurysms and artery dissections

Synonym
'Aneurysm', 'Dilated artery', 'Narrowed artery', 'Stenosis'

Research involving
Human

Sponsors and support

Primary sponsor: Catharina-ziekenhuis
Source(s) of monetary or material Support: PULS/e onderzoeksgroep;Technische Universiteit Eindhoven

Intervention

Keyword: AAA/Femoral Artery/Carotid Artery, Doppler Ultrasound, Fluid-Structure Interaction, Magnetic Resonance Imaging

Outcome measures

Primary outcome

Patient specific velocity profile over time and cross section of the abdominal aorta, carotid artery and femoral artery obtained with Ultrasound Doppler and compared with 4D flow MRI (abdominal aorta) or 2D PCMRI (femoral and carotid artery). This patient specific velocity profile will be used in FSI simulations of AAA's, carotid artery stenoses and femoral artery stenoses.

Secondary outcome

The secondary goal of this study is to validate the FSI model. With 4D flow MRI, the velocity streamlines can be constructed, which can then be compared to the streamlines from the FSI model. In addition, based on the velocity measured with 4D flow MRI, the Wall Shear Stress (WSS) and Oscillatory Shear Index (OSI) can be calculated, which can also be compared to the WSS and OSI as predicted by the FSI model. Also the with MRI measured wall displacements will be compared to the with FSI simulated wall displacements. Lastly, the 4D flow MRI data will also be used for the validation of the stiffness of the aortic wall.

Study description

Background summary

Cardiovascular diseases are the number one cause of death worldwide. Early diagnosis and treatment are therefore very important. There are two different types of vascular diseases: aneurysmal vascular disease (dilatation) and stenotic vascular disease (narrowing). An aneurysm can develop in different types of blood vessels, but most often occurs in the abdominal aorta. Rupture of an abdominal aortic aneurysm (AAA) is a major cause of death in the Western world, given the high mortality rate in case of rupture (80%). To prevent rupture, AAA patients visit the hospital every 3-12 months for a checkup, during which the diameter of the aneurysm is measured. Since AAA surgery is not without any risks, surgery is performed only when the rupture risk is greater than the surgery risk: the risk of complications during and after surgery. Currently, the rupture risk is based on the maximum diameter and growth rate of the aneurysm. Surgery is performed when the maximum diameter is greater than 5.5 cm or the diameter has increased more than 1 cm in one year. However, this criterion is not optimal, as there are cases where small aneurysms with a diameter of 3 cm have been ruptured and large aneurysms with a diameter of 7 cm that are still stable. Therefore, there is need for another method to be able to estimate the rupture risk better. With fluid-structure interaction (FSI) models we can model the blood flow through the aneurysm, from which we can derive for example the stress on the wall and the shear stress at the wall. These models already use a patient-specific geometry as measured with 3D Ultrasound. Research towards the hemodynamics in AAA's has shown that rupture occurs in areas of low wall shear stress. However, this is in contradiction with studies on the wall mechanics of AAA's, in which is shown that regions with a high wall stress are prone to rupture. Therefore, it can be concluded that the hemodynamics and wall mechanics do not provide enough information separately. In FSI simulations, the hemodynamics and wall mechanics are combined and these models could therefore help to improve the estimation of the rupture risk. Aneurysms can also occur in smaller blood vessels such as the femoral artery and carotid artery. However, a stenosis is more often found in these smaller blood vessels, which is caused by plaque formation (atherosclerosis). Research has shown that areas with a low wall shear stress are more prone to plaque formation. Therefore, the FSI models can also be used to estimate the stenosis progression and thus determine whether surgery is needed or not. Currently, a generic velocity profile over time and over the diameter of the blood vessel is used in these models. To further improve the estimation of the rupture risk and stenosis progression, this general velocity profile could be replaced by a patient-specific velocity profile. With Pulsed Wave and Color Doppler ultrasound, it is possible to measure the velocity of blood to obtain an inlet velocity profile over the cross section (Color Doppler) and over time (Pulsed Wave Doppler). However, a drawback of Ultrasound is that it is sensitive to noise and only the velocity in the direction of the

probe can be measured (angle dependent). As a result, it is not possible to distinguish the velocity in the axial direction (longitudinal direction of the blood vessel) from possible vortexes, which could interfere with the velocity measurement. With 4D Flow Magnetic Resonance Imaging (MRI), it is possible to measure the x- y- and z-components of the velocity in the blood vessel, which can be used to compare the velocity profile measured with Doppler Ultrasound with the MRI derived velocity profile. Because of the low resolution of 4D flow MRI, it is only applicable in larger blood vessels such as the aorta.
Therefore, for the smaller blood vessels 2D PCMRI will be used to compare the US-derived velocity profile. MRI is less sensitive to noise and this velocity profile can therefore be considered as the gold standard.

Study objective

Main goal:
The main goal of the study is to show the feasibility of using Doppler US derived patient specific velocity profile in the abdominal aorta, carotid artery and femoral artery, in order to improve the Fluid-Structure-Interaction models of AAAs, carotid artery stenoses and femoral artery stenoses. The velocity profiles will be compared to 4D flow MRI (abdominal aorta) or 2D PCMRI (femoral and carotid artery) derived velocity profiles.

Secundary goal:
The 4D Flow MRI can additionally be used to validate the FSI model. With 4D Flow MRI it is possible to reconstruct the streamlines of flow through the aneurysm, which can then be compared to the streamlines of flow through the aneurysm in the FSI simulations. In addition, from the measured velocity, the wall shear stress (WSS) and the oscillatory shear index (OSI) can also be determined with which the WSS and OSI calculated with the FSI simulation can be validated. Also the wall displacements can be derived from the MRI data, which can be compared to the simulated wall displacements with the FSI simulations. Lastly, the 4D flow MRI data will be used to validate the stiffness estimation of the aortic wall.

Study design

This is a study with AAA patients and patients with an asymptomatic stenosis of the carotid or femoral artery, who are under surveillance at the Catharina Hospital. In addition, 24 healthy subjects will also participate in the study. When the patient/volunteer agrees to participate in the study, a Pulsed Wave and Color Doppler ultrasound scan of the abdominal aorta, femoral artery or carotid artery will be performed. In addition, a 4D flow MRI (aorta) or 2D PCMRI (femoral and carotid artery) scan will be performed. Both scans do not use harmful radiation and therefore pose no risk to the patient/volunteer. In total, the examination will take approximately one hour. To minimize the time burden on the patient, an attempt will be made to schedule the additional

ultrasound and MRI examination right after the check-up.

Offline analysis will be performed on the Ultrasound and MRI data sets. Post-processing will be performed by the principal investigator, at and in collaboration with the Eindhoven University of Technology (TU/e).

Study burden and risks

Participation in this study provides no personal benefits to the patients and volunteers. The study will cost the patient approximately one hour of extra time. Non-harmful imaging modalities (Ultrasound and MRI) will be used during the study. The study is therefore without any risks. Only when a subject has metal implants, the MRI could cause damage. Therefore, the patients will be screened for metal implants in advance and those patients with a metal implant will be excluded from the study. Also for patients with claustrophobia, the MRI can be experienced as a burden. These subjects will therefore also not be included in the study.

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

The main inclusion criterium for the patients is that they have an abdominal aortic aneurysm or a femoral artery or carotid artery stenosis. Furthermore, the patients should be under surveillance at the Catharina hospital for their stenosis or aneurysm. For the AAA patients, an additional inclusion criterium is that they are involved in the longitudinal study (research mentioned in B2). The volunteers should be in the age of 18-65 and not diagnosed with a cardiovascular disease.

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. Furthermore, also patients and volunteers that suffer from claustrophobia will be excluded from the study. Lastly, the patients and volunteers will be screened for metallic foreign bodies. In case that metallic foreign bodies are present the patients and volunteers will not be included in the study.

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped

Start date (anticipated):	04-11-2022
Enrollment:	48
Type:	Actual

Medical products/devices used

Generic name:	Doppler Ultrasound and Magnetic Resonance Imaging
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	10-06-2022
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	07-07-2023
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	NL81219.100.22