Quantifying blood flow in the aorta using phase-contrast 4D flow MRI

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Obtain phased-contrast 4D flow MRI scans in 20 healthy volunteers to quantify local blood flow in the thoracic and abdominal aorta and extract boundary conditions for future in vitro studies. Furthermore, the 3D geometry of the vessels within...

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

Summary

ID

NL-OMON51196

Source
ToetsingOnline

Brief title
Quantifying blood flow in aorta

Condition

- Other condition

Synonym
Aorta blood flow; aorta and side branches' anatomy

Health condition

Blood flow dynamics in healthy aorta

Research involving
Human

Sponsors and support

Primary sponsor: University of Twente
Source(s) of monetary or material Support: Top Technology Twente;Connecting industry program (as part of coordinating investigator's PhD program)

Intervention

Keyword: Aorta, Blood flow, PC 4D flow MRI

Outcome measures

Primary outcome

To obtain blood flow boundary conditions from ascending aorta to internal and

external iliac arteries, including branched arteries such as subclavian

arteries, common carotid artery and visceral branch vessels. The main goal is

to acquire *volumetric flow rate*, *4D velocity fields (i.e., 3D spatial

coordinates and temporal points over the cardiac cycle)*, and *3D geometry of

the entire aorta and its side branches* in the aortic arch and abdomen FOVs.

Secondary outcome

Combining the obtained MRI data from aortic arch and abdomen regions, and

reconstruct a general aortic segmentation.

Study description

Background summary

Over the years, endovascular techniques have become the predominant treatment option for most infrarenal aortic aneurysms, but more recently also for complex aortic aneurysms such as juxtarenal abdominal aortic aneurysms (JAAA) and suprarenal abdominal aortic aneurysms (SRAAA). Moreover, several endovascular techniques were developed, which provide surgeons more treatment possibilities, for instance, chimney endovascular aortic repair (ChEVAR), Branched endovascular aortic repair (BEVAR) and Fenestrated endovascular aortic repair (FEVAR). However, rigorous investigations should be performed to determine their suitability and performance of various stent-grafts and configurations. One of the most critical investigational aspects is the influence of the stent-grafts on the blood flow trajectories inside and outside the treated region. By quantifying the blood flow, we will be able to determine local regions where flow complexity occurs, such as high shear, fluid stasis, and flow recirculations. These regions of great importance since they might be prone to unfavorable haemodynamics parameters, which could lead to (late) complications. To date, in-vitro flow phantom studies and computational fluid dynamics (CFD) simulations play essential roles in performing those studies, owing to their ability to visualize and quantify the flow fields inside the stent-grafts mimicking realistic properties of the in-vivo situation.

When performing such in vitro work, defining accurate and realistic flow boundary conditions is crucial in order to get realistic outcomes. In short, boundary conditions are defined as a set of constraints, such as pressure (gradient) values, velocity fields in the geometry*s boundaries (i.e., inflow, outflow and wall of arteries). In experimental studies, volumetric flow profiles in various aortic cross-sections will define the boundary conditions, with which blood flow can be determined in branched arteries throughout the aorta. Unfortunately, well-structured data and descriptions for aortic flow boundary conditions are not available in the literature. Therefore, researchers had to rely on boundary settings mentioned, whether in old analytical papers or obtained from animal studies.
In this study, we aim to perform phase-contrast (PC) 4D flow magnetic resonance imaging (MRI) over a cohort of healthy volunteers to acquire adequate human flow boundary conditions from the aortic arch to the internal/external iliac arteries, including branched arteries (i.e., subclavian arteries, common carotid artery, and visceral branch vessels). The obtained data will provide profound knowledge regarding actual flow profiles in different aortic segments of a healthy cohort, which is essential information to design more realistic and reliable in-vitro and/or CFD studies in the future. Thus, after completing the study and analyzing the data, the results will be published in a peer-reviewed journal. Ultimately, this provides the research community with insight into realistic blood flow boundary conditions.

Study objective

Obtain phased-contrast 4D flow MRI scans in 20 healthy volunteers to quantify local blood flow in the thoracic and abdominal aorta and extract boundary conditions for future in vitro studies. Furthermore, the 3D geometry of the vessels within investigated FOVs, starting from ascending aorta to internal/external iliac arteries, will be obtained by performing a separate MRI sequence.

Study design

An observational study will be performed in 20 healthy volunteers.

Study burden and risks

The included healthy volunteers have to visit the University of Twente for a single day. The entire procedure will take about 1.5 hours and consists of approximately 20 minutes of introduction followed by 50-60 minutes for performing the MRI scans, and around 5-10 minutes closure at the end of the study.
The present study carries no risks for the participant. The Siemens Magnetom Aera is used in clinical practice and judged to be a safe diagnostic procedure.

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

Healthy men or women, being older than 18 years.;
BMI <= 30.;
Willingness to undergo MRI scans.;
Signed informed consent (IC).

Exclusion criteria

Arithmetic heartbeat.;
Any history of cardiovascular disease
The standard MRI exclusion criteria (such as pacemakers, cerebral vascular clips, pregnancy, claustrophobia).

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	20-07-2022
Enrollment:	20
Type:	Actual

Ethics review

Approved WMO

Date:	22-07-2021
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	NL77332.091.21

Study results

Date completed: 27-10-2022

Actual enrolment: 20