4D Flow Quantification with MRI

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Primary Objective:• Intracardiac blood total flow and maximum flow velocity measured by 4D MR, and compared with 2D MR.Secondary Objective(s):• Intracardiac pressures as assessed by 4D MR , compared with 2D MR, invasive catheterization and...

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

Summary

ID

NL-OMON41077

Source
ToetsingOnline

Brief title
4D Flow Quantification with MRI

Condition

- Other condition
- Congenital cardiac disorders

Synonym
structural heart disease; Heart diseases

Health condition

Verworven structuele hartaandoeningen

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Blood flow and pressure assessment, Cardiac magnetic resonance (CMR), congenital heart disease, Intracardiac measurement

Outcome measures

Primary outcome

Intracardiac blood flow and flow velocity measured by 4D MR and compared with

2D MR.

Secondary outcome

• Intracardiac pressures as assessed by 4D MR, 2D MR, invasive catheterization

and echocardiography.

• Intracardiac shunting as assessed by 4D MR, 2D MR, invasive catheterization

and echocardiography.

Study description

Background summary

Measurement of intra-cardiac blood flow, flow velocities, abnormal flow in terms of valvular regurgitation or shunting, and flow-based estimation of intra-cardiac pressures are essential in the therapeutic management of patients with congenital and acquired heart disease. While direct intra-cardiac measurement of these parameters are considered as gold standard, in clinical practice non-invasive echocardiography with Doppler is preferred, particularly for repetitive measurements and follow-up. It is safe, portable, readily available, and is easy to perform. Echocardiography has practical limitations. It does not directly measure total blood flow, image quality depends on the experience of the operator and the acoustic accessibility of the patient, and some valves are difficult to assess by position (pulmonary valve) or the presence of foreign material (percutaneous valve implantations).
Cardiac magnetic resonance (CMR) has a growing role in the field of intra-cardiac blood flow measurements, particularly in adult congenital heart disease (ACHD). Cardiovascular MR flow is nowadays assessed with two-dimensional phase-contrast sequence (2D PC) which allows accurate assessment of total transvalvular flow, regurgitant fractions, regurgitant

volumes and shunt calculations. However, an MRI generally consists of a series of sequential scans, each relying on images from previous acquisitions. Not only is this time consuming, but also it is dependent on technician*s experience and often require direct supervision during planning by an experienced cardiovascular radiologist .This is particularly true in patients with congenital heart disease with complex and varied native and postsurgical anatomy. In addition, flow quantification is limited to the vessels targeted during the scan. Several factors can influence the accuracy of flow quantification, including the presence of complex flow and eddy-current phase offsets. With 2D PC , to measure blood flow in multiple vessels , multiple oblique plans have to be prescribed, which may lead to spatial aliasing, causing abrupt phase discontinuities in the images .
4D Flow is the new MR technique that might overcome these disadvantages. It allows scanning of the entire chest in approximately 7 minutes (depending on field of view, heart rate and resolution). The images may be reconstructed in any plane, avoiding the need to precisely defined cross-sectional planes during acquisition for each vessel. Occult jets or dynamic jets are easier detected. Also it does not require from the technician special knowledge of the complex anatomy. As opposed to 2D PC, there is no additional scan time required to evaluate other vessels in the imaging volume. With a volumetric data acquisition, spatial aliasing is easier to avoid, and thus eddy current correction can be more easily performed. Recently, arterial flow quantification has been shown to be more accurate and precise with 4DPC than 2DPC in congenital heart diseases. Ultimately, total examination could be shortened because all needed information (both contractile function and flow) is acquired in approximately 7 minutes. This will be an important improvement for patient comfort, special for patients with structural heart disease that have difficulties with breath holding and lying still in the magnet. This sequence does not require breath-holding. The only disadvantage for the moment is that the temporal resolution is lower than 2D PC which may affect accurate measurement of short lasting, high-velocity jets.

4D Flow in children with congenital, structural heart disease
Common protocols for the assessment of 2D flow in current clinical practice include atrioventricular valve planes, semilunar valve planes and large vessels. It is not uncommon in clinical practice to perform up to 6 or 8 2D flow measurements in a single study in a patient. A single 4D acquisition of flow encompassing flow in the heart and large vessels may be faster and more accurate and reproducible than traditional 2D flow measurements. This may results in important reductions of scan time, which is particularly important in children.
Preliminary studies have demonstrated that 4D Flow can better identify pulmonary and tricuspid insufficiency than echography and intracardiac shunts (ASD, patent foramen ovale, aortic baffle leak, VSD patch leak), some of which were not identified on 2D MR (1).
MR imaging is considered a safe imaging technique, that is clinically used in children. Cardiac MR is well established in the clinical care of children with

congenital heart disease at the Erasmus MC. The generation R population study illustrates that children tolerate MRI examinations well, also in the context of research. The sequence that we will investigate has been safely used at the Stanford University for more than 10 years, both in adults and children.
We will explain to the child and parents in an age-appropriate manner about the sequence and ask the child if he volunteers at the end of the clinical examination to lie in the magnet for 7 more minutes. The environment will be child friendly. Because it does not require breath-holding, the child can relax and listen to his favorite music.

Study objective

Primary Objective:
• Intracardiac blood total flow and maximum flow velocity measured by 4D MR, and compared with 2D MR.
Secondary Objective(s):
• Intracardiac pressures as assessed by 4D MR , compared with 2D MR, invasive catheterization and echography.
• Intracardiac shunting as assessed by 4D MR, compared with 2D MR, invasive catheterization and echography.

Study design

Prospective explorative study to assess intra-cardiac blood flow velocities using 4D MR. Comparative data will be used for technical validation: 2D MR, echocardiography, and invasive measurements, where they are available. The expected study duration is 12-18 months.

Study burden and risks

There are no additional risk for the participating patient. The sequence adds 7 minutes to the total duration of the scan.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Adults (18-64 years)
Children (2-11 years)
Elderly (65 years and older)

Inclusion criteria

•Men and women aged >18 years
Children between 8-12 years.
Children between 12-18 years.
• Clinical referral for CMR in the absence of any contraindication to MRI; Intra-cardiac flow measurements are part of the CMR indication.
• Signed informed consent.

Exclusion criteria

Any contraindication to an MRI scan or gadolinium contrast media (renal failure, allergy) per the policy of Erasmus University Medical Center Rotterdam.
• Inability or unwillingness to provide informed consent.

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-04-2014
Enrollment:	100
Type:	Anticipated

Ethics review

Approved WMO Date:	19-05-2014
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	01-12-2014
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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	NL48487.078.14