Clinical application of real-time three-dimensional echocardiography in pediatric cardiology; Emphasis on left ventricular function

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The primary aim of this study is to assess the applicability of RT3DE for the evaluation of left ventricular function in daily clinical practice of a pediatric cardiology service.

Ethical review	Approved WMO
Status	Will not start
Health condition type	Congenital cardiac disorders
Study type	Observational non invasive

Summary

ID

NL-OMON32547

Source
ToetsingOnline

Brief title
Real-time three-dimensional echocardiography in pediatric cardiology

Condition

- Congenital cardiac disorders
- Cardiac and vascular disorders congenital

Synonym
Congenital heart disease, heart function

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Sint Radboud

Source(s) of monetary or material Support: Combinatie: Subsidieaanvraag ligt ter beoordeling bij Nederlandse Hartstichting. Mogelijk tevens deels eerste geldstroom

Intervention

Keyword: Congenital heart disease, Pediatrics, Three dimensional echocardiography, Ventricular function

Outcome measures

Primary outcome

The duration of data acquisition and data analyses, the reproducibility

(intra-observer, inter-observer and test-retest variability), and the

capability of identifying changes in left ventricular ejection fraction. These

parameters will be compared for RT3DE and conventional echocardiography.

Secondary outcome

Not applicable.

Study description

Background summary

In children born with congenital heart disease (CHD), decreased ventricular function is an important predictor for morbidity and mortality. Therefore, careful monitoring of cardiac function, with the possibility to intervene therapeutically before heart failure becomes manifest, is essential in children with CHD. MRI is considered to be the standard for quantification of ventricular function. However, particularly in the pediatric age group MRI has important disadvantages like the need for general anaesthesia in order to lay down still during data-acquisition and the fact that it is not a bedside imaging technique. Consequently MRI is not practical for routine clinical use. Bedside measurements of ventricular function can be obtained by M-mode (1D) and 2D-echocardiography (2DE). These measurements are unreliable because they rely on geometric assumptions that do apply to normal hearts, but often not to diseased hearts. 3D-Echocardiography (3DE) can overcome these problems, since the entire left ventricle is imaged, obviating the need for geometric assumptions. In adults with normal and abnormal hearts, real-time 3DE (RT3DE) has been shown to be more accurate than 1D/2DE for quantification of

ventricular function and was extensively validated with MRI techniques. The use of RT3DE for ventricular quantification in children has hardly been investigated. Only a few small studies in selected pediatric patients have validated RT3DE measurements of ventricular function with MRI, but none have tested the clinical applicability of RT3DE for evaluation of ventricular function in daily practice. The hypothesis is that with the currently available, dedicated pediatric RT3DE hard- and software, ventricular function can be assessed in routine practice by RT3DE in pediatric patients with different kinds of CHD.

Study objective

The primary aim of this study is to assess the applicability of RT3DE for the evaluation of left ventricular function in daily clinical practice of a pediatric cardiology service.

Study design

Prospective feasibility study. In addition to the standard 2D echo-protocol, M-mode, 2D and 3D images will be made in order to measure left ventricular function. All patients will undergo three echocardiography*s; one before and twice after intervention. The first two echocardiography*s coincide with echocardiography*s performed for clinical reasons. Healthy volunteers will undergo two echocardiography*s, of which the first one will coincide with an echocardiographic examination performed for diagnostic purposes.

Study burden and risks

This study will be performed in patients under the age of 18, because the purpose of this study is to evaluate the clinical application of RT3DE in daily clinical practise of a pediatric cardiology clinic. The echocardiographic examinations coincide in the majority with echocardiography*s performed for diagnostic purposes. Echocardiography is not an invasive examination, doesn*t bring a burden and ultrasound waves have no vulnerable characteristics and bring therefore no health risks to the participating persons. The burden for the participating persons will mainly exist from one extra visit to our out patient clinic and an extra waiting time (10 minutes) on top of the standard echocardiographic examination.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Children (2-11 years)

Inclusion criteria

Patients:
- Age (< 18 years)
- Scheduled for a therapeutic cardiac intervention (surgical ro catheterisation) for one of the following four different diagnostic groups:
1. ventricular septal defects (VSD), n = 20, or
2. left ventricular outflow tract obstruction (LVOTO), n = 20, or
3. atrial septal defects (ASD), n = 20, or
4. right ventricular outflow tract obstruction, n = 20;Controls:
Age (<18 yr), Without cardiac anomalies

Exclusion criteria

Controls: Complains suiting acute illness, hemodynamic unstability
Patients: Complains suiting acute illness, hemodynamic unstability

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Will not start
Start date (anticipated):	01-04-2009
Enrollment:	100
Type:	Anticipated

Medical products/devices used

Registration:	No

Ethics review

Approved WMO

Date:	25-03-2009
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	NL24885.091.08