Standard and novel echocardiographic imaging techniques to assess cardiac dyssynchrony in pediatric patients with cardiac disease

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Routine evaluation of dyssynchrony in pediatric patients with cardiac disease is feasible using standard and novel echocardiographic techniques. The extent of cardiac dyssynchrony and its influence on cardiac function differs between groups of...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Congenital cardiac disorders
Study type	Observational non invasive

Summary

ID

NL-OMON33086

Source
ToetsingOnline

Brief title
Dyssynchrony in pediatric heart disease

Condition

- Congenital cardiac disorders
- Cardiac and vascular disorders congenital

Synonym
pediatric heart disease

Research involving
Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum
Source(s) of monetary or material Support: Nederlandse hartstichting

Intervention

Keyword: Dyssynchrony, Echocardiography, Pediatric heart disease

Outcome measures

Primary outcome

Parameters of dyssynchrony patients vs healthy controls: difference in time

from onset of QRS-complex to peak systolic velocity (TDI) or time to peak

systolic strain (speckle tracking) between at different sites within the

cardiac mass.

Secondary outcome

Not applicable

Study description

Background summary

Cardiac resynchronisation therapy (CRT) has emerged as a valuable tool in the management of patients with heart failure and QRS prolongation. Improvement in cardiac function, quality of life and life expectancy have been reported in the majority of patients who qualify for CRT.(1) Inclusion criteria for CRT used in large clinical trials are NYHA-class III to IV, QRS-duration >=120-130 ms and depressed left ventricular ejection fraction <= 35%. However, 20% to 30% of the patients who meet these criteria do not respond to CRT.(1) Effort has been made to better predict the success of CRT. Many single-centre studies evaluated inter-and intraventricular dyssynchrony, using various echocardiographic techniques and pointed out that the severity of left ventricular (LV)-dyssynchrony is a good predictor for response to CRT.(2-4) The results from the multicenter Prospect-study, however revealed that currently no single echocardiographic measurement assessing dyssynchrony can predict an improved response to CRT.(5) Recently, novel echocardiographic parameters have been proposed such as triplane tissue Doppler imaging,(6) real time 3D

echocardiography(7) and speckle tracking strain imaging,(8) which may better identify the potential responders to CRT. The excellent outcomes of CRT in selected adult patients have raised interest to apply CRT in pediatric patients with cardiac disease. Over the past decades the survival and life expectancy of pediatric patients with congenital and acquired heart disease has increased dramatically. However, in patients with corrected congenital heart disease, heart failure is one of the major causes of late mortality.(9) Data on the role of CRT in the management of heart failure in patients with a congenital heart defect are scarce. CRT has been used in the immediate post-operative period after correction of a congenital heart defect and improved cardiac output and narrowed QRS-duration were observed.(10-12) Furthermore, Dubin et al. evaluated the acute effect of CRT in chronic right ventricular (RV) failure and demonstrated the feasibility of RV-CRT in improving RV function and decreasing QRS-duration.(13) Reports on the long-term beneficial effects of CRT as treatment for chronic heart failure in children and adults with a congenital heart defect are limited.(14-16) Recently, a retrospective international multicenter study evaluated the use of CRT in paediatric patients with acquired or congenital heart disease.(17) One-hundred-and-three pediatric patients or patients with congenital heart disease in whom CRT was initiated were included and CRT induced increase in ejection fraction and decreased QRS-duration. Inclusion criteria were heterogeneous and only 54% of the patients met the criteria for CRT in adults.(17) Thus the criteria for initiation of CRT in the paediatric population and in adult patients with congenital heart disease are unclear. The large randomized adult CRT trials evaluated the effectiveness of CRT in patients with a mean age over 60 years with mostly ischemic heart disease. These data cannot simply be translated to a young population with either dilated cardiomyopathy or a wide variety of congenital heart defects . Cardiac failure in the pediatric population not only includes the failing LV but also the failing univentricular heart with either RV or LV morphology, the failing systemic RV in congenitally corrected transposition or after atrial switch procedure and the failing pulmonary RV in patients with corrected tetralogy of Fallot. In addition, substantial number of pediatric CRT candidates have cardiac failure related to conventional pacemaker therapy for postoperative or congenital atrioventricular block. In each of the above mentioned patient groups CRT has shown to be beneficial.(17) However, most pediatric studies also emphasize the need for better patient selection to avoid over- or underuse of CRT in children. Data in children on the role of evaluation of cardiac dyssynchrony to predict the response to CRT are very limited. Case reports and small case series in children

with CHD have demonstrated improved cardiac synchronization after CRT. Other

studies have evaluated the presence of cardiac dyssynchrony in adult patients with (repaired) congenital heart disease.(18;19) Data on the evaluation of cardiac dyssynchrony in pediatric patients with cardiac disease is scarce and most of the standard and novel echocardiographic techniques to assess dyssynchrony are no part of the routine echocardiographic examination of pediatric patients. Therefore, the extent of cardiac dyssynchrony, the role of dyssynchrony in cardiac dysfunction and the evolution of dyssynchrony over time are unclear in the specific groups of pediatric patients with congenital or acquired heart disease.

Reference List

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Study objective

Routine evaluation of dyssynchrony in pediatric patients with cardiac disease is feasible using standard and novel echocardiographic techniques.
The extent of cardiac dyssynchrony and its influence on cardiac function differs between groups of pediatric patients with specific cardiac disease.
In each specific patient group of pediatric patients with cardiac disease dedicated criteria for initiation of CRT should be published.

Study design

prospective patient based study

Study burden and risks

Echocardiography is a non-invasive and safe imaging tool and poses no risks of any damage. The burden is minimal as the patient/healthy controls is examined in the supine position during 60 minutes.

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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

Pediatric pts with specific heart disease as mentioned above

Exclusion criteria

The inability to undergo an echocardiographic examination

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:	Recruitment stopped
Start date (anticipated):	01-10-2009
Enrollment:	120
Type:	Actual

Ethics review

Approved WMO

Date:	09-06-2009
Application type:	First submission
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)

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	NL26774.058.09