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Analysis of heart muscle shape using cardiovascular magnetic resonance imaging

Submission date
04/08/2019

Recruitment status
No longer recruiting

Registration date
27/11/2019

Overall study status
Completed

Last Edited
26/04/2021

Condition category
Circulatory System

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

Plain English Summary
Background and study aims
Measuring myocardial (heart muscle) strain is of growing interest in cardiovascular magnetic resonance (CMR) imaging for the detection of subclinical myocardial dysfunction in heart disease. The aim of this study is to assess the age and gender-related reference values of myocardial strain in healthy adults and to evaluate the influence of field strength and postprocessing software.

Who can participate?
Data collected in previous studies using CMR were analysed in this study (healthy volunteers aged over 18)

What does the study involve?
CMR data is analysed to find differences in the results of the analysis using different software and different strengths of scanning devices.

What are the possible benefits and risks of participating?
None

Where is the study run from?
Working Group on Cardiovascular Magnetic Resonance, Experimental and Clinical Research Center, a joint cooperation between the Charité University Medicine Berlin and the Max-Delbrueck Center for Molecular Medicine, and HELIOS Klinikum Berlin Buch, Department of Cardiology and Nephrology, Berlin, Germany

When is the study starting and how long is it expected to run for?
January 2018 to July 2019

Who is funding the study?
Charité – Universitätsmedizin Berlin (Charité University Medicine Berlin) (Germany)

Who is the main contact?
Prof. Jeanette Schulz-Menger
edyta.blaszczyk@charite.de

Contact information

Type(s)
Scientific

Contact name
Prof Jeanette Schulz-Menger

ORCID ID
http://orcid.org/0000-0003-3100-1092

Contact details
Charité University Medicine Berlin Campus Buch Working Group Kardiale MRT Lindenberger Weg 80
Berlin
Germany
13125
+49-30-450540615
edyta.blaszczyk@charite.de

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Nil known

Study information

Scientific Title
Quantification of myocardial strain assessed by Cardiovascular Magnetic Resonance feature tracking in healthy subjects – influence of post-processing

Study hypothesis
A retrospective study of strain analysis to establish standards for image acquisition and interpretation and to add further knowledge in this regard by analysing the influence of scanner field strength and analysis software package on age- and gender-related reference values of myocardial strain

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 04/11/2010 and 17/07/2014, ethical committee of the Charité Medical Faculty (Charité – Universitätsmedizin Berlin, Campus Charité Mitte, Charitéplatz 1, 10117 Berlin, Germany; Tel: +49 (0)30 450 517 222; Email: ethikkommission@charite.de), ref: (EA2/077/10), EA1/058/13, DOI, 0.1161/CIRCIMAGING.116.005242

Study design
Retrospective proof of concept trial

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Hospital

Study type(s)
Diagnostic

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

Condition
Myocardial strain in healthy volunteers

Interventions
The researchers screened healthy subjects, who were prospectively examined in former studies. The ethical committee Charite approved all of the studies. All participants were enrolled after informed consent was obtained.

CMR was applied at a 1.5 and 3 T Scanner (Siemens Healthcare, Erlangen, Germany) using a 32 channel surface coil. Cine imaging is performed applying state of the art steady state precession sequences to determine the global cardiac performance in three long axis and short axis.

It is a retrospective trial to evaluate the reference values of myocardial strain applying cardiovascular magnetic resonance (CMR) by analysing the influence of scanner field strength, analysis software package, age- and gender-related factors. This proof of concept trial is intended to extend the indications for CMR.

Subjects were divided into three age groups: group 1 aged < 35 years, group 2 aged 35-55 years and group 3 aged > 55 years

Only volunteers with similar cine protocols were included. Feature tracking analysis was performed using CVI42 software (prototype version 5.3.0, Circle Cardiovascular Imaging Inc., Calgary, Canada). All images were additionally analyzed with TomTec Image Arena (version 1.3.0.91, TomTec Imaging Systems GmbH, Unterschleissheim, Germany).

Statistical analyses were performed using IBM SPSS Statistic version 23 (IBM, Armonk, US). The researchers calculated mean values and standard deviation (SD) for demographic parameters, LV function and strain measurements. Volumes were indexed to body surface area (BSA) and height. Non-parametric Mann-Whitney-U-Test for unpaired samples was used for comparisons of strain parameters between gender, analysis software and field strength. Age-related differences were analyzed using the non-parametric Kruskal-Wallis-Test. Differences were considered statistically significant at $p < 0.05$.

Intervention Type
Other

Primary outcome measure
1. Longitudinal strain assessed in three long-axis views: 4CV, 3CV and 2CV
2. Circumferential strain and radial strain assessed short-axis full coverage
Measured using CMR at a single timepoint

Secondary outcome measures
There were no secondary outcome measures

Overall study start date
01/01/2018

Overall study end date
01/07/2019

Eligibility

Participant inclusion criteria
1. Healthy male and female aged > 18 years
2. Preserved left ventricular ejection fraction in echocardiography
3. Willingness to undergo CMR
4. Willingness and ability to follow directions and complete all study procedures as specified in the protocol

Participant type(s)
Healthy volunteer

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
The researchers screened 243 healthy subjects, 67 healthy subjects were included

Total final enrolment
67

Participant exclusion criteria
1. Any known cardiovascular risk factor
2. History of cardiac disease
3. Impaired LV ejection fraction (LVEF) (< 55%)
4. Pathologic findings in CMR
5. Incomplete CMR data for feature tracking analysis (less than three long axis and three short axis views) led to exclusion

Recruitment start date
01/01/2013

Recruitment end date
08/11/2017

Locations

Countries of recruitment
Germany

Study participating centre
Charité University Medicine Berlin
Working Group Kardiale MRT
Lindenberger Weg 80
Berlin
Germany
13125

Sponsor information

Organisation
Charité University Medicine Berlin

Sponsor details
Working Group Kardiale MRT
Lindenberger Weg 80
Berlin
Germany

13125
+40-30-450-540-615
edyta.blaszczyk@charite.de

Sponsor type
University/education

Website
http://www.cmr-berlin.org

ROR
https://ror.org/001w7jn25

Funder(s)

Funder type
University/education

Funder Name
Charité – Universitätsmedizin Berlin

Results and Publications

Publication and dissemination plan
Results of this study shall be published in a high-ranking peer-reviewed journal.

Intention to publish date
30/10/2020

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are not expected to be made available due to reasons of data protection laws in Germany. However, upon request methodology and dataset structure can be shared.

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		01/06/2021	26/04/2021	Yes	No