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Comparison of heart workload during exercise after a Ross procedure and a mechanical valve replacement

Submission date
27/05/2021

Recruitment status
No longer recruiting

Registration date
07/07/2021

Overall study status
Completed

Last Edited
08/07/2021

Condition category
Circulatory System

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
An aortic valve replacement is a type of open heart surgery used to treat problems with the heart's aortic valve. The aortic valve controls the flow of blood out from the heart to the rest of the body. An aortic valve replacement involves removing a faulty or damaged valve and replacing it with a new valve made from synthetic materials or animal tissue.
The choice of the better substitute for aortic valve replacement (AVR) in young adults (age <60 years) remains challenging. In this population, mechanical valve or Ross procedure are the most common options.

Our hypothesis is that the workload of the left ventricle of the heart after an AVR may be lower after a Ross procedure when compared to a mechanical prosthesis. In this observational study, we aim to compare the left ventricular function and workload at rest and during exercise between patients who underwent AVR with a mechanical prosthesis or a Ross procedure. A group of healthy volunteers will serve as a control group.

Who can participate?
All adults (between 18 and 64 years old) who underwent an AVR with a mechanical prosthesis or a Ross procedure between 2008 and 2016 at the Montreal Heart Institute could be included in absence of exclusion criteria.

What does the study involve?
This is an observational, non-interventional study.
The study protocol involves 3 visits to the Montreal Heart Institute. The first visit consists of a clinical assessment, an explanation of the study protocol, and a questionnaire about physical activities. The second visit is dedicated to stress tests and echocardiography at rest and during exercise. The participant will have to cycle on an ergocycle during the test. On the third visit, the participant will undergo a stress cardiac magnetic resonance imaging study.

What are the possible benefits and risks of participating?
During the stress test or during exercise, the participant can have symptoms such as chest pain,

dyspnea, palpitations. The risk of serious events such as ventricular arrhythmias during a stress test is very low. During the study, a previously unknown abnormal condition could be detected. In such circumstances, the participant will be referred immediately to his most responsible physician for further investigations.

Where is the study run from?
The study will be run at the Montreal Heart Institute, Montréal, Canada.

When the study starting and how long is it expected to run for?
January 2016 to March 2019

Who is the funding of the study?
Department of Cardiac Surgery of the Montreal Heart Institute.

Who is the main contact?
Dr. Pierre-Emmanuel Noly, noly.pierreemmanuel@gmail.com

Contact information

Type(s)
Scientific

Contact name
Dr Pierre-Emmanuel Noly

ORCID ID
https://orcid.org/0000-0001-6600-1258

Contact details
Montreal Heart Institute
Department of cardiac surgery
5000 rue Belanger
Montreal
Canada
H1T1C8
+1 5143763330
pierre-emmanuel.noly@icm-mhi.org

Type(s)
Scientific

Contact name
Dr Ismail El-Hamamsy

Contact details
The Mount Sinai Hospital
1 Gustave L. Levy Place
New York
United States of America

10029-6574
+1 212-241-6500
ismail.El-hamamsy@mountsinai.org

Additional identifiers

Protocol serial number
RACE-2015-1865

Study information

Scientific Title
Ross Assessment and Cardiac workload during Exercise trial

Acronym
RACE trial

Study objectives
Left ventricular workload during exercise might be lower after aortic valve replacement with a pulmonary autograft (Ross procedure) compared to a mechanical prosthesis.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 21/07/2015, Montreal Heart Institute Research Ethics Committee, (5000, rue Bélanger, Montréal Québec, H1T 1C8 I, Canada; +1 514 376-3330; no email provided), ref: FWA00003235

Primary study design
Observational

Study design
Single-center observational case-control matched study

Study type(s)
Other

Health condition(s) or problem(s) studied
Effect of exercise on the heart in patients who underwent a surgical aortic valve replacement with either a mechanical prosthesis or a Ross procedure

Interventions
For patient selection, 2 cohorts of patients who underwent aortic valve replacement with either a Ross procedure or a mechanical prosthesis were matched according to age, sexe, aortic valve disease, and date of surgery. All the participants (healthy volunteers, Ross group, mechanical AVR group) underwent subsequently an echocardiography at rest and during a stress test (VO2 max) and a cardiac magnetic resonance imaging during exercise. After study inlcusion, every participant had 2 appointments, one for echocardiography and stress test ans another for MRI.

1. Echocardiography at rest and during a stress test:
Rest echocardiograms were performed with participants in a semi-supine position. Similarly, exercise echocardiograms were carried out in a semi-supine position using an ergocycle. Maximal cardiopulmonary exercise tests were performed on a semi-supine cycle ergometer. Starting initially at 20W, the workload was increased every 2 minutes in successive stages of 20W until the maximal effort was reached or at a maximum workload of 240W. Participants were asked to maintain a steady pedaling speed of 60 RPM. Peak effort was followed by a 5-minutes recuperation period. Gas exchange parameters were continuously measured at rest, during exercise, and during recovery.
The duration of the test was 1 hour.

2. Cardiac Magnetic Resonance Imaging at rest and during exercise with MRI-compatible ergocycle.
All the participants underwent a CMRI at rest and during exercise. The same stress test protocol was used (an increase of 20W every 2 minutes). The duration of the test was 2.5 hours.

Intervention Type
Behavioural

Primary outcome(s)
Left ventricular workload estimated by the valvulo-arterial impedance (Zva) measured at rest and during exercise.
(The valvulo-arterial impedance equals the sum of the systolic blood pressure (sBP) and the mean aortic valve gradient divided by the stroke volume index: Zva= [sBP + mean AV gradient] / Stroke volume index. All the 3 parameters are measured at the same time during echocardiography and CMRI.)

Key secondary outcome(s)
1. Energy Loss Index (ELI) calculated as [(AVAxAa)/(Aa-AVA)]/BSA at rest and during exercise
2. Aortic valve area (AVA) measured by transthoracic echocardiogram (TTE) and MRI at rest and during exercise
3. Ascending aorta crossectional area (Aa) measured by TTE and MRI at rest and during exercise
4. Left ventricular stroke work (LVSW) calculated as (MAP + mean AV gradient) x Stroke volume x 0.0136
at rest and during exercise
5. Aortic valve gradients measured by TTE and MRI at rest and during exercise
6. LV diameters and volumes measured by TTE and MRI at rest and during exercise
7. LV ejection fraction measured by TTE and MRI at rest and during exercise
8. MAP, systolic arterial pressure, diastolic arterial pressure, heart rate at rest and during exercise

Completion date
30/03/2019

Eligibility

Key inclusion criteria
All adults between 18 and 64 years old who underwent AVR with mechanical prosthesis or with Ross procedure at our institution between 2007 and 2016.

Participant type(s)

Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

Total final enrolment
50

Key exclusion criteria
1. Uncontrolled hypertension at rest (>150/90 mmHg)
2. LVEF <50%
3. Contra-indication to exercise
4. Cardiac surgery within the last 3 months
5. Pregnancy
6. Severe pulmonary hypertension (systolic pulmonary arterial pressure > 50 mmHg)
7. Atrial fibrillation
8. Cardiovascular complications (stroke, transient ischemic attack, myocardial infarction, pericardial effusion, heart failure, malignant arrhythmias) within the last 3 months
9. Patients with a permanent pacemaker
10. More than moderate mitral insufficiency
11. Contraindication to MRI
12. Impossibility to perform a stress test on an ergocycle (limiting physical capacities)

Date of first enrolment
01/03/2016

Date of final enrolment
29/03/2019

Locations

Countries of recruitment
Canada

Study participating centre
Montreal Heart Institute
5000 rue Belanger Est
Montreal
Canada
H1T1C8

Sponsor information

Organisation
Montreal Heart Institute

ROR
https://ror.org/03vs03g62

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Institut de Cardiologie de Montréal

Alternative Name(s)
Montreal Heart Institute, MHI, ICM

Funding Body Type
Private sector organisation

Funding Body Subtype
Research institutes and centers

Location
Canada

Results and Publications

Individual participant data (IPD) sharing plan
All data generated or analysed during this study will be included in the subsequent results publication. All the data are acquired and stored (paper and numerical) at the Montreal Heart Institute for a duration of 10 years as required by our local IRB. If the datasets are required during the processes of publication, we will provide the data after anonymization.

IPD sharing plan summary
Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?

Participant information sheet	version v2	08/07/2021	No	Yes