Systolic phases with laminar and turbulent flow in peripheral arteries of patients with congenital valvular aortic stenosis

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In a way, the turbulence elicited by blood passing the stenotic valve can be seen as 'labeling' the ejection phase of the heart. This makes it possible to distinguish this phase from the presumed phase of arterial contraction. Systematic...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Cardiac valve disorders
Study type	Observational non invasive

Summary

ID

NL-OMON51209

Source
ToetsingOnline

Brief title
Systolic phases in aortic stenosis

Condition

- Cardiac valve disorders

Synonym
stenotic heart valve

Research involving
Human

Sponsors and support

Primary sponsor: Martini Ziekenhuis

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: aortic, flow, stenosis, turbulence

Outcome measures

Primary outcome

The presence or absence of turbulence in blood flow velocity measurements in

proximal are distal arteries.

De phase during systole that turbulence is observed.

Secondary outcome

timing of stroke onset at different measuring points in the arterial system

with respect to the R-peak of a simultaneously recorded QRS-complex

Study description

Background summary

Blood flow velocity measurements in patients with congenital aortic valvular stenosis contains a certain amount of turbulence when measured distal to the stenosis. This turbulence spreads over the arterial tree and can be measured or heard by means of duplex ultrasonography.
In the past a single subject observation was made that this turbulence does not contain the full duration of systole but may be preceded by a brief period of non/turbulent or laminar flow. This observation, when confirmed in a larger series, may provide new insight in the physiology of the cardiovascular system. It may support the theory of acceleration, formulated in 2014, that during the first few instances the ejection phase of the heart is supported by a brief contraction within the arterial tree that travels like a peristaltic wave along its branches enabling the pressure of cardiac contraction to reach out into all the bodies capillary systems.

Study objective

In a way, the turbulence elicited by blood passing the stenotic valve can be seen as 'labeling' the ejection phase of the heart. This makes it possible to

distinguish this phase from the presumed phase of arterial contraction. Systematic research describing these two phases may provide support or denial to the theory of arterial acceleration.

Study design

Measuring bloodflow velocity in different locations within the arterial tree in patients with a congenital aortic valve stenosis who are enlisted for aortic surgery. Patients with a severe aortic valve stenosis will be operated (valve replacement or valve reconstruction). The patients will be examined prior to as well as after surgery. Patients with a moderate stenosis will not be operated but are nevertheless investigated twice with a 3 month interval. Finally, a control group of patients without aortic valve stenosis will also be investigated twice with a 3 month interval.
By describing flow velocity patterns qualitatively measurements are assessed on the presence of turbulence within proximal and distal arteries. By comparing preoperative with postoperative measurements it will be investigated whether turbulence decreases as expected after succesfull surgery.

Study burden and risks

Participants are twice asked to come to the Martini Hospital in Groningen for an ultrasound investigation of 90 min. duration.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

moderate (5) or severe (5) congenital valvular aortic stenosis or patients who were proven to have no valvular aortic stenosis (5)

Exclusion criteria

atrial fibrillation

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:	Recruiting
Start date (anticipated):	20-02-2022
Enrollment:	15
Type:	Actual

Ethics review

Approved WMO Date:	28-07-2021
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

ID: 19990
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL77569.042.21