Effect of atrial pacing right ventricular function after openheart surgery

Published: 28-09-2020
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To investigate the effects of atrial pacing on right ventricular function and hemodynamics after open heart surgery.

Ethical review	Not approved
Status	Will not start
Health condition type	Myocardial disorders
Study type	Observational non invasive

Summary

ID

NL-OMON48174

Source
ToetsingOnline

Brief title
Outpace-study

Condition

- Myocardial disorders
- Cardiac therapeutic procedures

Synonym
myocardial stunning

Research involving
Human

Sponsors and support

Primary sponsor: Medisch Centrum Leeuwarden
Source(s) of monetary or material Support: Stichting Onderzoek Intensive Care

Intervention

Keyword: Atrial pacing, Hemodynamics, Open heart surgery, Right ventricular function

Outcome measures

Primary outcome

right ventricular ejection fraction (RVEF)

Secondary outcome

cardiac index (CCI)

mean pulmonary arterial pressure (MPAP)

central venous pressure (CVP)

mixed venous saturation (SvO2)

right ventricular enddiastolic volume index (EDVI)

right ventricular stroke volume index (RVSVI)

right ventricular stroke work index (RVSWI)

left ventricular stroke work index (LVSWI)

systolic, diastolic and mean arterial pressure (MAP).

Study description

Background summary

Temporary pacing with an external pacemaker after open heart surgery * besides preventing arrhythmias and AV-conduction disorders * is used to improve cardiac output. In theory, postoperative stunning temporarily limits stroke volume and SA-node dysfunction compromises an adequate compensatory rise in heartrate to ensure sufficient cardiac output. There is a lack of consensus regarding the use of this form of pacing. Protocols vary widely between hospitals. Moreover, the scientific base for this form of pacing mainly comprises studies dating back to the nineteen sixties and seventies. Major changes in (operating) techniques have taken place since then. Also, the role of the right ventricle in this context has not been studied specifically. The current study aims to

investigate the effects of atrial pacing on right ventricular function specifically and hemodynamics in general, in today*s postoperative setting. We hypothesize that a reduction in heart rate may lead to decreased right ventricular function.

Study objective

To investigate the effects of atrial pacing on right ventricular function and hemodynamics after open heart surgery.

Study design

A prospective non-randomized, non-blinded interventional study, in which patients will act as their own controls.

Intervention

When a hemodynamically stable state is achieved, the external pacemaker will be switched off for 30 minutes. Hemodynamic parameters will be acquired directly prior to switching off, 15 respectively 30 minutes after switching off, and 15 minutes after switching back on. To gain insight in the natural course of stunning, this routine will be repeated the next morning. No additional hemodynamic interventions will be allowed in these periods.

Study burden and risks

The study population is selected to minimize burden and risks. All required (measuring-) equipment is part of the standard perioperative protocol. The only additions will be the intervention itself (two periods without pacing). During the first period patients will still be sedated, so it will not consciously affect them. During the second period patients may experience dizziness due to bradycardia. For safety reasons the intervention will be terminated in case of development of hypotension (MAP < 60 mmHg). Length of stay in the intensive care unit will not be negatively affected. Study subjects do not directly benefit form this study, however, they will contribute to possible improvement in treatment of future patients. .

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- Age * 18 years old
- Post open on-pump cardiac surgery
- Swan Ganz catheter in situ
- Hemodynamic stability (optimal rescusitation; expected no-touch period of 45 minutes)
- Atrial pacing

Exclusion criteria

- Hypotension (MAP < 60 mmHg)
- Active bleeding ((* 200 cc/hour)
- Atrial malsensing/malpacing
- Ventricular or DDD-paced rythm
- Atrial fibrillation
- AV-conduction dysorders (2nd or 3rd grade AV-blocks)
- Sinusrythm * 80 beats/min (hemodynamic effects of increasing heartrate to 90 beats/min will probably be limited)
- Presence of internal pacemaker
- Severe tricuspid valve regugitation

- Intracardiac shunt (unreliable Swan Ganz measurements)

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	21
Type:	Anticipated

Ethics review

Not approved

Date:	28-09-2020
Application type:	First submission
Review commission:	RTPO, Regionale Toetsingscie Patientgebonden Onderzoek (Leeuwarden)

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	NL68550.099.19