

The effect of ventricular unloading on the T-wave

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The main objective in this study is to determine whether there is an effect of acute unloading of the left ventricle on the ECG, in particular the T-wave.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Cardiac disorders, signs and symptoms NEC
Study type	Observational non invasive

Summary

ID

NL-OMON39221

Source

ToetsingOnline

Brief title

UNLOAD-T study

Condition

- Cardiac disorders, signs and symptoms NEC

Synonym

ECG, T-wave

Research involving

Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum

Source(s) of monetary or material Support: AMC/AMR

Intervention

Keyword: Impella, mechano-electrical feedback, repolarization, T-wave

Outcome measures

Primary outcome

Change of BSM integral maps of the QRST- and STT-interval

Secondary outcome

Several other variables associated with the T-wave and derivable from the BSM.

These variables include the non-dipolar content of the integral maps, T-wave amplitude, T-wave duration, T-peak to T-end interval (TpTe), QRS duration, QT-interval, isochrones in the body surface map, QRS integral map, and dispersion in these values.

Study description

Background summary

The electrocardiogram (ECG) is the most important diagnostic tool in cardiology, measuring electrical activity in the heart. T-wave abnormalities are associated with e.g. ischemia, repolarization disorders and arrhythmias which may lead to sudden cardiac death. The (patho)physiological background of the T-wave and its alterations however, is not beyond debate. Many studies have been conducted to examine the exact genesis of the T-wave. Notwithstanding that multiple factors may affect the morphology of the T-wave, the majority of these studies are solely focused on the dispersion in repolarization of the action potential. The heart however, is a contracting and relaxing muscle which suggests that, beside electrical factors, mechanical factors may be of importance as well. Examination of the effect of cardiomechanics on the morphology of the T-wave may contribute to a better understanding of T-wave genesis and consequently an improvement of the diagnostics of repolarization disorders and the associated risk for arrhythmias. In order to elucidate the effect of cardiomechanics on the ECG in the in vivo human heart, we selected a moment in which an abrupt change in ventricular work load occurs, and structural remodelling is absent. In the catheterisation lab, acute unloading of the heart takes place during impella guided percutaneous coronary interventions. Therefore we selected this moment to make body surface maps (BSMs; multiple lead ECGs) recordings in order to assess whether any changes occur, and whether mechano-electrical feedback plays a role in vivo

Study objective

The main objective in this study is to determine whether there is an effect of acute unloading of the left ventricle on the ECG, in particular the T-wave.

Study design

Observational

Study burden and risks

The PCI procedure will be extended with 15-20 minutes extra time (10 minutes for preparation and application of electrodes, plus 5-10 minutes for the BSM measurements). This includes one extra stepwise increase in pump settings and one stepwise decrease. This all is not accompanied by extra risks for the patient. In some cases shaving of the thorax is necessary to obtain good contact of electrodes with the skin. The electrodes of the BSM system might cause skin reactions such as irritation and itching. There will be no extra fluoroscopy time due to measurements. The BSM electrode strips are radio-translucent and do not influence the PCI procedure.

Contacts

Public

Academisch Medisch Centrum

Meibergdreef 9
Amsterdam 1105 AZ
NL

Scientific

Academisch Medisch Centrum

Meibergdreef 9
Amsterdam 1105 AZ
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)

Elderly (65 years and older)

Inclusion criteria

Patients undergoing an elective percutaneous coronary intervention (PCI) with a supportive Impella placement.

Exclusion criteria

Unstable rhythm: atrial fibrillation (AF); Frequent occurrence of ventricular or atrial extra systoles (VES, AES); Ventricular tachycardias (VTs).

Study design

Design

Study type: Observational non invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Basic science

Recruitment

NL

Recruitment status: Recruitment stopped

Start date (anticipated): 02-05-2013

Enrollment: 25

Type: Actual

Ethics review

Approved WMO

Date:	19-02-2013
Application type:	First submission
Review commission:	METC Amsterdam UMC

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	NL37678.018.12