Measurement of Short-term Variability of Activation-Recovery Interval on Human Intracardiac Signals

Published: 12-12-2017
Last updated: 12-04-2024

The primary objective of the study is to explore the possibilities measurement of STV-ARI on human intracardiac signals, to compare this with the STV-QT on the surface ECG during sinus rhythm and while pacing the heart with different frequencies.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Cardiac arrhythmias
Study type	Observational non invasive

Summary

ID

NL-OMON48872

Source
ToetsingOnline

Brief title
STV-ARI clinical study

Condition

- Cardiac arrhythmias

Synonym
sudden cardiac arrest, ventricular arrhythmias

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Activation-recovery interval, ICD, intracardiac EGM, STV

Outcome measures

Primary outcome

Short-term variability of repolarization (STV) of 30 consecutive beats is measured from different recording sites (ECG, RV EGM, LV EGM, unipolar & bipolar signals). STV is claculated with the formula *|D(n+1)-Dn |/30×*2, where D represents the repolarization duration and n the number of complexes, in this case 30 complexes. The repolarization duration is defined and measured differently per recording site. All intracardiac and ECG leads can be recorded simultaneously.

- STV-QT: QT-interval is defined as the interval from the beginning of the Q-wave until the end of the T-wave.
- STV-ARI: repolarization duration is defined as the interval from the minimal dV/dt of the QRS complex to the maximum or minimum dV/dt of the T wave, depending on the morphology of the T-wave.

Secondary outcome

-- Age at implantation;

- Sex;

- Left ventricular ejection fraction (LVEF) measured by MRI, nuclear imaging or echocardiography;

- NYHA class;

- Underlying cardiac disease (ischemic cardiomyopathy, dilated cardiomyopathy,

other);

- Cardiovascular risk factors(smoking, hypertension, diabetes mellitus,

peripheral artery disease, COPD)

- Relevant comorbidities (COPD, chronic kidney disease, malignancy)

- Medications (beta blockers, ACE-inhibitors/AT2-antagonists, aldosterone

antagonists, diuretics, calcium blockers, digoxin, class I or III

anti-arrhythmic drugs)

- ECG parameters (RR-interval, PQ-interval, QRS-duration, QRS-morphology,

RV-pacing: yes/no)

Study description

Background summary

Sudden cardiac death (SCD) caused by ventricular tachyarrhythmias, such as sustained ventricular tachycardia (VT) and ventricular fibrillation (VF) remains an important health problem in the Western world. Multiple randomized controlled trials, like MADIT II or SCD-HeFT, have demonstrated a survival benefit of implantation of an implantable-cardioverter defibrillator (ICD) in patients with a reduced left ventricular ejection fraction (LVEF) who are at high risk of developing ventricular arrhythmias. Since these landmark trials, ICD implantation has become a class I recommendation in international guidelines for patients with reduced LVEF below 35% due to ischemic and non-ischemic cardiomyopathy. Nevertheless, while ICD-therapy as anti-tachycardia pacing and shocks, are highly effective in prevention of SCD by termination of sustained arrhythmias, they do not prevent VT/VF from occurring. Additional treatment, such as anti-arrhythmic drugs or radiofrequency (RF) ablation, are often used as adjunctive therapy to reduce the number of ICD-shocks.

It would therefore be more effective if the device could detect if arrhythmias are impending and initiate pacing therapy to prevent the arrhythmia and thus the ICD-shock from occurring. This requires continuous monitoring of the arrhythmogenic potential of the patient to alert the device when a patient becomes highly susceptible to ventricular arrhythmias.

In an arrhythmogenic animal model it has been shown that beat-to-beat variability, measured as short-term variability (STV) of the activation recovery interval or ARI of the intracardiac EGM, increases abruptly prior to occurrence of arrhythmias. In this study we want to explore the potential of STV-ARI measurements on human intracardiac signals.

Study objective

The primary objective of the study is to explore the possibilities measurement of STV-ARI on human intracardiac signals, to compare this with the STV-QT on the surface ECG during sinus rhythm and while pacing the heart with different frequencies.

Study design

This study will be a cross-sectional, non-invasive, observational study with one time point of observation. The study will be performed in patients that are scheduled for ICD implantation at the UMC Utrecht, with a lead in the right atrium and the right ventricle. During the implantation procedure, additional measurements will be performed, for which no additional invasive procedures are needed. No additional follow-up or tests have to be scheduled.

Study burden and risks

The measurements will add approximately 15 minutes extra time to the duration of the procedure but will not lead additional risk of harm or discomfort to the patient. The only (minor) risks present in the current study are related to the implantation itself which follows standard procedures.

Contacts

Public
Universitair Medisch Centrum Utrecht

Yalelaan 50
Utrecht 3584 CM
NL
Scientific
Universitair Medisch Centrum Utrecht

Yalelaan 50
Utrecht 3584 CM
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

In order to be eligible to participate in this study, a subject must have an indication for an ICD according to ESC guidelines published in 2016:
- Secondary prophylaxis for sudden cardiac death (SCD) and ventricular tachycardia (VT), - Primary prophylaxis for SCD and VT
- Left ventricular ejection fraction (LVEF) <35% and New York Heart Association (NYHA) functional class II, III, despite adequate medical therapy.
- LVEF <30% and NYHA class I, despite adequate medical therapy, - A dual chamber system with a lead in the right atrium (RA) and the right ventricle (RV)
- Elective replacement of the device (for example due to battery depletion)
- Sinus rhythm at implantation

Exclusion criteria

A potential subject who meets any of the following criteria will be excluded from participation in this study:
- Age < 18 years
- QRS-duration >120 ms
- Contra-indications for ICD-implantation
- Permanent atrial fibrillation
- Atrioventricular block, 2nd and 3rd degree

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	13-02-2018
Enrollment:	20
Type:	Actual

Ethics review

Approved WMO Date:	12-12-2017
Application type:	First submission
Review commission:	METC NedMec
Approved WMO Date:	28-11-2018
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	30-12-2019
Application type:	Amendment
Review commission:	METC NedMec

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	NL62580.041.17

Study results

Date completed:	31-12-2020
Actual enrolment:	27