Spatial Resolution of Pace-Mapping using Automated Template Matching for Site of Origin Identification of Idiopathic Outflow Tract Premature Ventricular Contractions

Published: 10-08-2018
Last updated: 12-04-2024

1. Assess the spatial resolution of pace-mapping using the PaSoTM software to identify the site of origin of outflow tract idiopathic PVCs2. Compare the spatial resolution of pace-mapping using the PaSoTM software for PVCs originating from the RVOT…

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Cardiac arrhythmias
Study type	Observational invasive

Summary

ID

NL-OMON55404

Source
ToetsingOnline

Brief title
Pace-mapping for outflow tract PVC ablation

Condition

- Cardiac arrhythmias

Synonym
Heart Rhythm Disorder, Ventricular Arrhythmia

Research involving
Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum

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

Intervention

Keyword: Automated Template Matching, Outflow Tract, Pacemapping, Premature Ventricular Contractions (PVC)

Outcome measures

Primary outcome

- Site of ablation success (RVOT vs LVOT).

- Local activation time during PVC at each pacing site

- Percentage of pace-match correlation calculated by PASOTM software at each

pacing site

Secondary outcome

- Presence/absence of reversed polarity at the site of ablation success

- Secondary endpoint: Ablation success 3 months after the procedure, determined

by Holter and defined as a reduction in PVC burden >80%

Study description

Background summary

Radiofrequency catheter ablation (RFCA) for the treatment of idiopathic premature ventricular complexes (PVC) arising from the right ventricular outflow tract (RVOT) or left ventricular outflow tract (LVOT) is a highly effective alternative to anti-arrhythmic drugs.1 Endocardial activation mapping is typically the preferred approach to identify the PVC site of origin (SoO) and guide RFCA.3*5 However, activation mapping is limited when PVCs are infrequent or absent during the procedure. Particularly in these cases, pacemapping can provide a useful alternative to activation mapping.3,4,6 Former studies evaluating the accuracy of pacemapping for identifying the SoO of idiopathic PVCs are limited by the expected high intra and inter-observer variability associated with the solely visual assessment of pacematches (*eyeballing*) and the insufficient applicability to daily clinical practice of in-house developed pacematching softwares.3,7,8 Moreover, there is very limited

data regarding the accuracy and clinical usefulness of pacematching in patients with LVOT PVCs, as most of the studies included pacemapping data from patients with RVOT PVCs only.

The automated digital pace matching module PaSoTM, integrated in the CARTO 3 System (Biosense Webster, Diamond Bar, CA) aims to improve accuracy and efficacy of pacemapping in PVC ablation by automatically and therefore objectively comparing pacemapping induced signals with arrhythmia signals. To date, the clinical significance of the PaSoTM software that is easily applicable to every electroanatomical mapping (EAM) procedure using the CARTO 3 system has not been demonstrated.

Study objective

1. Assess the spatial resolution of pace-mapping using the PaSoTM software to identify the site of origin of outflow tract idiopathic PVCs
2. Compare the spatial resolution of pace-mapping using the PaSoTM software for PVCs originating from the RVOT vs. PVCs arising from the LVOT
3. Define the optimal template matching cut-off value for the percentage of correlation that predicts the site of ablation success
4. Define the efficacy and clinical usefulness of solely pacemapping with the PaSoTM software as primary ablation approach in patients with infrequent PVCs.

Study design

This will be a single-center prospective observational study.

Study burden and risks

In all patients, the electrophysiological study and mapping procedure will be clinically indicated and scheduled before inclusion in the study. The technique will be performed according to current standards. The only change introduced by this protocol will be a slightly longer procedure time. During procedures *down time* regularly exists: time in which mapping data is reviewed, before ablation is performed. As much as possible the data collection for this protocol will be conducted in this *down time* and as such will not add additional procedural time. If it is not possible to collect data during *down time* the procedure will be lengthened by a maximum of 30 minutes.

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

- Acceptance for catheter ablation of frequent PVC.
- Pre-procedural 12-lead ECG documentation of PVCs with a suspected site of -origin in the right or left ventricular outflow tract based on the PVC morphology (right bundle branch of left bundle branch morphology and inferior axis)
- Absence of structural heart disease (assessed by echocardiography).

Exclusion criteria

- Age < 18 years
- Inadequate patient competence
- Pregnancy
- Presence of structural heart disease (e.g., prior myocardial infarction, non-ischemic cardiomyopathy, infiltrative cardiac disease such as sarcoidosis, amyloidosis, arrhythmogenic right ventricular cardiomyopathy/dysplasia, hypertrophic cardiomyopathy, non-compaction cardiomyopathy and congenital heart

disease)

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	14-09-2018
Enrollment:	30
Type:	Actual

Ethics review

Approved WMO

Date:	10-08-2018
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO

Date:	31-01-2021
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

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	NL63634.058.17