# MANual vs. automatIC Local Activation Time Annotation for Guiding Premature Ventricular Complex Ablation Procedures (MANIaC-PVC Study).

# A randomized, multicenter study.

NCT ID                                    **Not yet available**

DATE OF THE DOCUMENT                       **November 7, 2017**

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# Tabla de contenido

## 1. BACKGROUND

Premature ventricular complexes (PVCs) are a frequent target for catheter ablation. Conventional mapping of ventricular tachycardia (VT) requires that the operator accurately detects the local activation time (LAT) in unipolar (U-EGM) and/or bipolar electrograms (B-EGM). The maximal –dV/dt in the U-EGM coincides with the arrival of the depolarization wavefront directly beneath the electrode. Furthermore, the morphology of the unipolar recording indicates the direction of wavefront propagation. However, the major disadvantages of U-EGMs are susceptibility to noise and the presence of substantial far-field signal, [1], which limit their routine use during activation mapping. In B-EGMs, the far-field signal is subtracted out, facilitating the identification of local activation signal, which coincides with the initial peak of the B-EGM [2]. Drawbacks to B-EGMs include being influenced by wavefront direction, bipole orientation, electrode size, and interelectrode spacing [3]. Furthermore, LAT assessment on B-EGMs is often challenging, especially in cases with low-voltage EGMs with multiple components.

Given these limitations of conventional assessment of LAT in both bipolar and unipolar EGMs, increasing efforts have attempted to develop automatic algorithms for activation mapping. Recently, El Haddad et al described an automated algorithm that detects the maximal –dV/dt in the U-EGM within the window demarcated by the B-EGM that achieved the highest accuracy in algorithmic mapping of atrial and ventricular tachycardia[4]. This algorithm, once integrated into an electroanatomical navigation system, allows the automatic annotation of the LAT during activation mapping. However, data about its utility and accuracy in PVC ablation procedures are scarce. A recent study by our group[5] including 40 patients that underwent PVC ablation showed that the correlation between manual LAT annotation by expert electrophysiologists and automatic annotation by the Wavefront system was good. However, WF-annotation systematically underestimated LAT, especially in LVOT. In terms of accuracy in the SOO identification, the effective RFp was equally well identified with both annotation approaches. However, a randomized study comparing ablation guided by conventional LAT annotation vs. guided by automatic LAT annotation should be performed in order to confirm the efficacy of Wavefront-guided annotation during PVC ablation procedures.

The present randomized study aims to analyze the accuracy of this novel algorithmic method, based on automatic annotation of the maximal negative slope of the U-EGM within the window demarcated by the B-EGM (Wavefront, CARTO, Biosense Webster, Diamond Bar, CA, USA) by comparison with conventional manual annotation in a multicenter cohort of patients referred for PVC ablation. Further on, the automatic annotation of LAT will be aided by the ECG recognition pattern algorithm (included in the last version of CARTO), which is intended to avoid wrong annotation of ventricular complexes other than the clinical PVC. This automatic acquisition process

(LAT and ECG pattern) will be referred to from now on as WF-method. We hypothesize that automatic LAT annotation using WF-method could be superior to conventional, manual annotation in terms of mapping success and could reduce both procedure time and radiofrequency time.

## 2. STUDY PURPOSE

### 2.1 STUDY DESIGN

This is a prospective, randomized, controlled and international multicenter study.

### 2.2 RANDOMIZATION

All patients who fulfill the inclusion criteria will be consecutively enrolled and randomized on a 1:1 basis to each of the LAT annotation systems (WF vs. M-method) before the ablation procedure. Ablation will be directed to the earliest activation site identified with the assigned annotation system. Any change of the assigned annotation system during the procedure will not be allowed, thus being a reason for justifying study exclusion. The only exception will be considered when using the WF-method, if annotation is misleading due to the presence of atrial far-field signals in the selected window of interest (see section 4.5.3). In those cases, whether elimination of the acquired point or manual reannotation will be admitted, after description of the issue.

### 2.3 OBJECTIVES

In order to assess the potential benefits of automatic instead of manual LAT annotation during ablation procedures of premature ventricular complexes (PVCs), the following objectives will be assessed:

1. To compare the ability of both annotation systems (WF vs. M-method) to accurately identify the PVC site of origin (SOO) and propagation pattern. To compare the rates of mapping success (see definition in the next section) between both methods.

2. To assess other procedural outcomes obtained from both annotation systems: Procedure time, mapping time, RF time, number of RF applications.

3. To compare the clinical outcomes (PVC burden at one month after procedure) between both annotation approaches.

### 2.4 DEFINITIONS

- **Mapping success**: It will be defined as complete PVC abolition after RF applications at the earliest activation site (EAS) identified using the assigned mapping approach. A maximum of 2 RF applications with appropriate parameters (contact force, impedance drop, catheter stability) during a maximum of 45 seconds will be allowed. If the PVC is not abolished after 2 RF applications with appropriate parameters, mapping will not be considered successful.

- **Acute procedure success**: It will be defined as complete elimination of the PVC at the end of the procedure.

- **Target point**: It will be defined as any suspected PVC-SOO where RF is delivered according to mapping data. Therefore, for one case there can be found a single target point with multiple RF applications, or multiple target points with one single RF application. The maximum distance between 2 RF applications to be considered at the same target point will be defined as 5 mm (equivalent to a 1-cm$^2$ area[6]).

- **First mapped chamber**: It will be defined as the first cardiac chamber where the operator decides to perform electroanatomical mapping according to electrocardiographic (PVC morphology) and clinical criteria. In the case of PVCs arising from ventricular outflow tracts, we propose an algorithm (see Appendix C) to avoid subjective criteria, and to deal with eventual wrong selection of the first mapped chamber, leading to unnecessary RF applications.

## 2.5 ENDPOINTS

### 2.5.1 PRIMARY ENDPOINT

The primary endpoint will be mapping success using the assigned mapping approach, as defined in the previous section.

### 2.5.2 SECONDARY ENDPOINTS

The following secondary endpoints will be considered:

1. Mapping time.
2. Number of mapped chambers.
3. Accuracy of proposed algorithm (see Appendix C) for selection of first chamber to map.
4. Number of target points.
5. RF time.
6. Number of RF applications.
7. Acute procedure success, as defined in the previous section.
8. Clinical success (reduction of, at least, 80% in the 24-hour PVC burden one month after the procedure).

## 2.6 PATIENT SELECTION CRITERIA

### 2.6.1 INCLUSION CRITERIA

Patients meeting all the inclusion criteria and none of the exclusion criteria could be considered for inclusion in the study. Patients can only be asked to participate if all of the following criteria apply:

- Age > 18 years.
- Indication for PVC ablation.

- Signed informed consent.

Patients will be excluded from the study if they meet any of the following criteria:
- Age < 18 years.
- Pregnancy.
- PVC ablation procedures guided by pacemapping (PASO® module); eg. low burden of PVCs during the study, mechanical impact during activation mapping.
- Impossibility to perform activation mapping with the required density of points in the region of interest (see section 4.5.3).
- Concomitant investigation treatments.
- Medical, geographical and social factors that make study participation impractical, and inability to give written informed consent. Patient's refusal to participate in the study.

## 2.7  STUDY SIZE AND DURATION

100 patients with drug refractory PVCs will be consecutively enrolled and randomized on a 1:1 basis to each of the LAT annotation systems (WF vs. M-method). For more details about sample size calculation, see section 5.1.

An enrollment log with all the patients included in the study, even drops out, will be collected. Data will be collected at enrollment, baseline and at one-month follow-up visit. The total recruitment time will be approximately 12 months (from 5 experienced centers; see next section). The total follow-up time will be one month for each patient. Therefore, the total study duration will be approximately 13 months. Accordingly, the estimated completion date will be approximately by the end of 2018.

# 3. STUDY INVESTIGATORS

## 3.1 STUDY INVESTIGATORS AND PARTICIPATING CENTERS

This clinical study will be conducted by qualified investigators who have proven experience with PVC ablation procedures and clinical studies. The following investigators and centers will participate:

1. **Dr. Antonio Berruezo**. Hospital Clínic, Barcelona (Spain). Mail: BERRUEZO@clinic.cat

2. **Dr. Felipe Bisbal**. Hospital Universitari German Trias i Pujol, Badalona (Spain). Mail: f.bisbalvb@gmail.com

3. **Dr. Alonso Pedrote**. Hospital Universitario Virgen del Rocío, Sevilla (Spain). Mail: pedroteal@hotmail.com

4. **Dr. Juan Fernández-Armenta**. Hospital Universitario Puerta del Mar, Cádiz (Spain). Mail: juanfdezarmenta@gmail.com

5. **Dr. Diego Penela**. Ospedale Guglielmo da Saliceto, Piacenza (Italy). Mail: dpenela30@gmail.com

## 3.2 COORDINATING CLINICAL INVESTIGATOR

The following investigator will be the study Coordinating Clinical Investigator:

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# 4. PROTOCOL DESCRIPTION

## 4.1 PROTOCOL PROCEDURES AND OVERVIEW

The following table lists study activities that will be performed at each scheduled visit for all patients enrolled:

| PROCEDURES \ VISIT | Enrollment | Baseline | Randomization 1:1 | Ablation | Pre-discharge | 1 Month (+10 days) |
|---|---|---|---|---|---|---|
| Informed Consent | √ | | | | | |
| Inclusion/Exclusion criteria | √ | | | | | |
| Re-evaluation Inclusion/exclusion criteria | | √ | | | | |
| Demographic Data | | √ | | | | |
| Medical History | | √ | | | | |
| Pre-procedure MRI (if available) | | √ (*) | | | | |
| Cardiovascular medication | | √ | | | √ | √ |
| Transthoracic Echocard. (TTE) | √ | | | | √ (*) | √ |
| Ablation Data (RF, time, etc.) | | | | √ | | |
| Randomization | | | √ | | | |
| NYHA class | | √ | | | | √ |
| 12 lead ECG | | √ | | | | √ |
| 24-hour Holter | √ | | | | | √ |
| BNP/NT-proBNP | √ | | | | | √ |
| Protocol Deviation | √ (*) | √ (*) | √ (*) | √ (*) | √ (*) | √ (*) |
| Adverse Event | √ (*) | √ (*) | √ (*) | √ (*) | √ (*) | √ (*) |
| Termination | √ (*) | √ (*) | √ (*) | √ (*) | √ (*) | √ (*) |

(*) If applicable

**Table 1:** List of all investigational specific activities/procedures.

## 4.2 PROTOCOL FLOW

The flow chart of the protocol is the following:
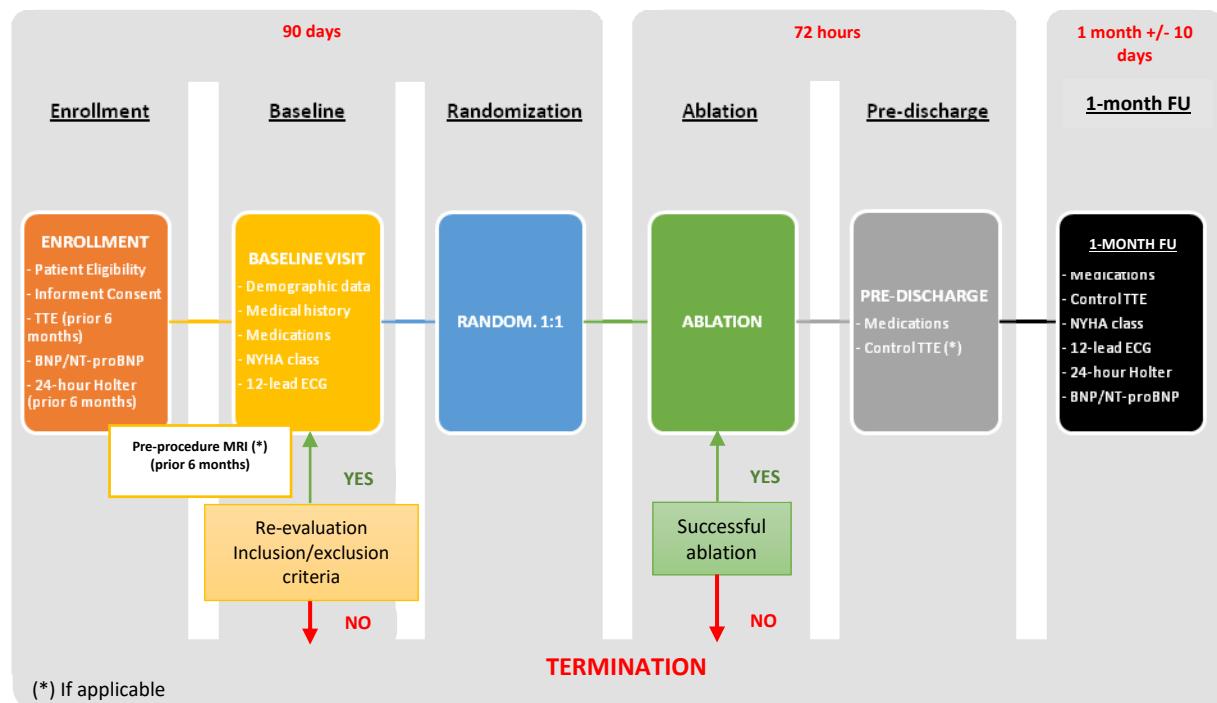


**Figure 1:** Study flow chart.

## 4.3 ENROLLMENT VISIT

### 4.3.1 FIRST TASKS

During the Enrollment visit the following tasks will be completed:

- Patient eligibility check (inclusion/exclusion criteria). Only patients that meet all of the inclusion criteria and none of the exclusion criteria can be approached to participate.
- Patient agrees in participate and signs and dates the patient informed consent.
- Prior reports of cardiac imaging studies (transthoracic echocardiography and/or cardiac magnetic resonance imaging) will be collected, as specified in sections 3.3.2 and 3.3.3.
- Once the patient agrees to participate, a blood test will be given to determine basal levels of BNP or NT-proBNP (according to local hospital policies).
- Once the patient agrees to participate, antiarrhythmic drugs and beta-blockers have to be withdrawn at least for 5 half-lives before the procedure.

### 4.3.2 TRANSTHORACIC ECHO REQUIREMENTS

A local hospital transthoracic echocardiography (TTE) performed within the previous 6 months of the ablation procedure will be required. The following measurements will be collected:

- LVEF (biplane Simpson's method) (%)
- LVEDD and LVESD (paraesternal long axis 2D) (mm)
- LVEDV and LVESV (biplane Simpson's method) (mL or mL/m$^2$)

Of note is that three consecutive averaged beats will have to be computed to minimize distortion generated in case of frequent PVCs during exploration. The echocardiographic evaluation will not include ectopic or post-ectopic cycles.

### 4.3.3 CARDIAC MRI REQUIREMENTS

If available, a local hospital cardiac magnetic resonance imaging (MRI) would be advisable, also within the previous 6 months. If not performed before, it can be scheduled in the enrollment or baseline visits as long as it is suitable according to hospital characteristics. Image acquisition protocols must include late gadolinium enhancement (LGE) sequences. The following measurements will be collected:

- LVEF (%)
- LVEDD and LVESD (mm)
- LVEDV and LVESV (mL or mL/m$^2$)
- Presence, location (subendocardial, intramyocardial, subepicardial, transmural) and distribution (linear, patchy, etc.) of LGE, if any.

## 4.4  BASELINE VISIT

The baseline visit must be performed after the patient has signed the informed consent form and prior to the PVC ablation procedure. The patients will be evaluated clinically and the following data will be collected and procedures performed:

- Patient demographic data

- Clinical evaluation with a physical examination

- Medical and cardiovascular history

- Pre-procedure MRI (optional, see before)

- Current cardiac medication (antiarrhythmic drugs and beta-blockers should have been withdrawn at least for 5 half-lives before the procedure)

- NYHA class assessment

- 12-lead ECG

- Adverse Events Notification (if applicable)

- Protocol Deviation (if applicable)

- Termination (if applicable)


## 4.5 RANDOMIZATION AND ABLATION

### 4.5.1  RANDOMIZATION

Patients will be randomly assigned to each of the annotation systems (WF vs. M-method) on a 1:1 basis before the procedure as described in chapter 2.2.

### 4.5.2  ELECTROPHYSIOLOGIC STUDY

Electroanatomical mapping (EAM) will be performed using the CARTO® navigation system (Biosense Webster, Diamond Bar, CA) with a 3.5-mm irrigated tip catheter (NaviStar® ThermoCool® or ThermoCool® SmartTouch®, Biosense Webster). During the procedure, 12-surface ECG and intracardiac recordings will be displayed by an electrophysiology data acquisition system (Bard LabSystem, CR Bard Inc, Lowell, MA; or EP-Tracer, CardioTek, Maastricht, The Netherlands).

### 4.5.3  ACTIVATION MAPPING. ANNOTATION SYSTEMS.

The cardiac structures that will be targeted during activation mapping will be decided according to PVC morphology in surface ECG and operator's criteria. A detailed activation map of the cardiac chamber/s suspected to contain the SOO of the will be performed in all patients:

- In those cases with a suspected outflow tract origin, mapping will be guided by a proposed algorithm (see Appendix C) that includes a previously described clinical score[7] (1 point for

each of the following: hypertension, male gender, age > 50 years). With this algorithm, an accurate prediction of left vs. right ventricular outflow tract origin is expected.

- After applying the previous algorithm and having completed RVOT mapping, if a focus outside the RVOT is suspected, subsequent mapping of the coronary sinus may be advisable to add useful information of the left side and possible epicardial origin of the PVCs.

- The minimum density of points required to obtain an acceptable map will be defined as a fill threshold of < 6 mm in the 20-ms isochronal area containing the earliest activation site (area of interest), and < 10 mm for the chamber of interest.

An ECG surface lead with a well-defined R-wave peak (R peak = 0 ms) will be used as the reference to perform the activation EAM. For both annotation systems, the end of the window of interest will be set at the end of the PVC-QRS to avoid the annotation of atrial far-field signals (in cases with retrograde conduction of the PVC). During activation mapping, points will be acquired only after a 2-second period of catheter stability. Activation mapping of additional anatomical structures will be allowed under operator criteria, in cases where the suspected SOO could not be located at the initially mapped chamber. Regardless of the number of structures mapped during the procedure, the annotation system will be the one assigned at the beginning of the procedure. The earliest activation site (EAS) will be considered to be located at the point with the highest precocity relative to the earliest onset of PVC on the 12-lead surface ECG, when activation mapping has concluded.

### 4.5.3.1 MANUAL ANNOTATION (M-METHOD):

A detailed electrocardiogram (ECG)-gated activation map of the chamber of interest will be acquired using the CARTO system. An experienced electrophysiologist will perform the annotation of LAT in each acquired point. The LAT will be measured from the onset of B-EGM (earliest positive or negative deflection) of the distal bipole of the mapping catheter to the defined reference. The use of the U-EGM as a guidance to identify the real onset of B-EGM will be decided under electrophysiologist criteria.

### 4.5.3.2 AUTOMATIC ANNOTATION (WF-METHOD):

The annotation of LAT in each acquired point will be automatically performed using the LAT annotation tool integrated into CARTO system, Wavefront (WF). Automatic annotation of LAT performed by the CARTO system uses the maximum negative slope of the distal U-EGM to set the timing of the mapping annotation, displayed on the corresponding B-EGM. Additionally, the automatic annotation of LAT will be aided by the ECG recognition pattern

algorithm (included in the last version of CARTO), which is intended to avoid wrong annotation of ventricular complexes other than the clinical PVC.

### 4.5.4 ABLATION

Ablation will be directed to the earliest activation site identified with the assigned annotation system. A target point will be defined as any suspected PVC-SOO, where RF is delivered, according to mapping data. The temperature limit will be set at 45ºC. Power limit will be set according to the anatomical structure containing the SOO: 40 W for the RVOT and the subvalvular LVOT, 30-40 W in the aortic root, and 20 W in the coronary sinus. If RF application is successful, it will be maintained for 60 seconds in cases of RVOT PVCs, and for 30-45 seconds when PVCs arise from the LVOT or distal CS. The point at which radiofrequency application is successful will be tagged as the effective RFp (e-RFp). If PVCs persist after a 30-second application, RF delivery will be stopped and another target point will be selected for further applications. Any additional RF applications located within a 6-mm distance from the first application will be considered as part of the same target point–suspected SOO. On the contrary, all RF applications located beyond this 6-mm distance will be considered as additional target points.

## 4.6 PRE-DISCHARGE

The pre-discharge visit must be performed within 3 days of the ablation procedure and before the patient is discharged from hospital. For all patients, the following procedures must be performed:

- Adverse Events Notification (if applicable)
- Protocol Deviation (if applicable)
- Termination (if applicable)

Regarding medications prior discharge, antiarrhythmic drugs will not be reinitiated after the procedure. A control TTE will be advisable in case any procedure-related complication is suspected. Otherwise, it is not required as per protocol.

## 4.7 ONE-MONTH FOLLOW-UP

Clinical follow-up will include an outpatient clinic visit one month after ablation procedure. 12-lead ECG and 24-hour ambulatory Holter monitoring will be performed. Successful ablation will be defined as at least an 80% reduction in the 24-hour burden of PVCs at one month post-procedure, since recurrences may be detected very soon after the catheter ablation.[8]

# 5. STATISTICAL METHODS

## 5.1 SAMPLE SIZE

For sample size calculation, a superiority design was assumed. Null hypothesis is considered at the outset that the two annotation methods (M- and WF-methods) are on average equal in terms of mapping success (as defined in section 2.4), whereas the alternative hypothesis states that the proposed annotation methods are not equal. Based on historical controls, the acute mapping success was considered to be about 60% for the M-method, and 85% for WF-method. The Type I error was set to a value of 5%. The Type II error was set equal to 20%, with a statistical power of 80%. Given these assumptions, a sample size of 98 is estimated (49 patients per group).

## 5.2 STATISTICAL ANALYSIS

Statistical analysis will be performed using SPSS (version 23, SPSS Inc., Chicago, IL). Continuous variables will be expressed as mean $\pm$ SD or median (range), and will be compared with the Student t test. For categorical variables, data will be expressed as percentages. Proportions will be compared with $\chi^2$ test. Differences will be considered statistically significant when p <0.05.

# APPENDIX A: References

1.      Stevenson WG and Soejima K. Recording techniques for clinical electrophysiology. *J Cardiovasc Electrophysiol*. 2005;16:1017-22.
2.      Liuba I and Walfridsson H. Activation mapping of focal atrial tachycardia: the impact of the method for estimating activation time. *J Interv Card Electrophysiol*. 2009;26:169-80.
3.      Ndrepepa G, Caref EB, Yin H, el-Sherif N and Restivo M. Activation time determination by high-resolution unipolar and bipolar extracellular electrograms in the canine heart. *J Cardiovasc Electrophysiol*. 1995;6:174-88.
4.      El Haddad M, Houben R, Stroobandt R, Van Heuverswyn F, Tavernier R and Duytschaever M. Novel algorithmic methods in mapping of atrial and ventricular tachycardia. *Circ Arrhythm Electrophysiol*. 2014;7:463-72.
5.      Acosta J, Soto-Iglesias D, Fernández-Armenta J, Frutos-López M, Jáuregui B, Arana-Rueda E, Fernández M, Penela D, Alcaine A, Cano L, Pedrote A, Berruezo A. Clinical Validation of Automatic Local Activation Time Annotation during Focal Premature Ventricular Complex Ablation Procedures. Europace. 2017. (ACCEPTED, AHEAD OF PUBLICATION, submission EUPC-D-17-00694R1)
6.      Andreu D, Berruezo A, Fernandez-Armenta J, Herczku C, Borras R, Ortiz-Perez JT, Mont L and Brugada J. Displacement of the target ablation site and ventricles during premature ventricular contractions: relevance for radiofrequency catheter ablation. *Heart rhythm : the official journal of the Heart Rhythm Society*. 2012;9:1050-7.
7.      Penela D, De Riva M, Herczku C, Catto V, Pala S, Fernandez-Armenta J, Acosta J, Cipolletta L, Andreu D, Borras R, Rios J, Mont L, Brugada J, Carbucicchio C, Zeppenfeld K and Berruezo A. An easy-to-use, operator-independent, clinical model to predict the left vs. right ventricular outflow tract origin of ventricular arrhythmias. *Europace : European pacing, arrhythmias, and cardiac electrophysiology : journal of the working groups on cardiac pacing, arrhythmias, and cardiac cellular electrophysiology of the European Society of Cardiology*. 2015.
8.      Penela D, Van Huls Vans Taxis C, Aguinaga L, Fernandez-Armenta J, Mont L, Castel MA, Heras M, Tolosana JM, Sitges M, Ordonez A, Brugada J, Zeppenfeld K and Berruezo A. Neurohormonal, structural, and functional recovery pattern after premature ventricular complex ablation is independent of structural heart disease status in patients with depressed left ventricular ejection fraction: a prospective multicenter study. *Journal of the American College of Cardiology*. 2013;62:1195-202.

## APPENDIX B: Data collection sheet

**PATIENT ID**: ………………………………………………………………………………………………………………………………

**ABLATION DATE**: ……… /……… /………

**CENTER:** Clínic / German Trias i Pujol / Virgen del Rocío / Puerta del Mar / Guglielmo da Saliceto

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**DEMOGRAPHICS:**

- **DOB:** ……… /……… /………            - **Age**: ……………            - **Sex**: M / F

- **Height**: …………… cm            - **Weight**: …………… Kg

- **Hypertension**: NO / YES            - **Diabetes**: NO / YES

- **Dyslipidemia**: NO / YES            - **Smoker**: NO / YES

- **COPD**: NO / YES            - **Sleep apnea**: NO / YES

- **CLINICAL SCORE** (1 point for: HTA, male, > 50 y.o.) = …………

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**HEART DISEASE:**

- **Cardiomyopathy**: Ischemic / Valvular / Idiopathic / Hypertensive / Other: …………………………………………

- **Ischemic cardiomyopathy**: Anterior / Inferior / Lateral / Septal / RV myocardial infarction

- **NYHA Functional Class**: I / II / III / IV

- **ICD**: NO / YES: Primary / Secondary prevention

- **Atrial fibrillation**: NO / YES: Paroxysmal / Persistent / Long-lasting / Permanent

- **Conduction disease**: NO / YES: ……………………………………………………

- **Basal QRS duration** (ms): …………

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**PVC MORPHOLOGY:**

- **Monotopic:** YES / NO            - **PVC-QRS duration**: ………… ms

- **PVC coupling interval:** ………… ms            - **¿Fixed coupling interval?:** NO / YES

- **Axis**: Superior / Inferior || Left / Right            - **Transition**: V1 / V2 / V3 / V4 / V5 / V6

- **24-h Holter % of PVCs:** ……………            - **24-h Holter number of PVCs:** …………………

- **Other morphologies/Notes**: ………………………………………………………………………………………………………

**MEDICATIONS:**

- **Betablockers**: (………………………) Dose (…………) - **Amiodarone**: NO / YES: Dose (………...)

- **Flecainide**: NO / YES: Dose (………...)          - **Digoxin**: NO / YES: Dose (………...)

- ACEI: (………………………) Dose (…………)          - **ARA-II**: (……………………………) Dose (…………)

- **Spironolactone**: NO / YES: Dose (………...)          - **Furosemide**: NO / YES: Dose (………...)

- **Others**: ………………………………………………………………………………………………………………………………………

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**IMAGING AND BLOOD TESTS:**

**ECHOCARDIOGRAPHY:**

- **LVEF** (Simpson 4C): ……… %

- **LVEDD**: ……… mm          - **LVESD**: ……… mm

- **LVEDV**: ……… mL          - **LVESV**: ……… mL

- **Segmental wall motion abnormalities**: NO / YES: Segments: ………………………………………………….

- **Significant valvular disease**: NO / YES: Specify: ……………………………………………………………………


**MRI:**

- **MRI MODALITY:** 1.5 Tesla / 3 Tesla

- **LVEF** (Simpson 4C): ……… %

- **LVEDD**: ……… mm          - **LVESD**: ……… mm

- **LVEDV**: ……… mL          - **LVESV**: ……… mL

- **Location of LGE**: Subendocardial / Intramyocardial / Subepicardial / Transmural

- **Distribution of LGE**: Linear / Patchy / Others: ………………………………………………….


**CARDIAC CT:** NO / YES


**BLOOD TESTS:**

- **BNP**: ………… pg/mL          - **NT-proBNP**: ………… pg/mL

**ABLATION PROCEDURE:**

**- Annotation system**: MANUAL / WAVEFRONT

**- Ablation catheter:** Navistar ThermoCool / ThermoCool SmartTouch

**- Deflectable sheath (Agilis):** NO / YES

**- First vascular access:** Femoral artery / femoral vein


**MAPPING DATA:**

**- First mapped chamber**: RVOT / LVOT / Coronary sinus / Tricuspid annulus / Mitral annulus

**- Sublocation of 1ˢᵗ mapped chamber**: …………………………………………………………….………

**- Additional mapped chambers (sort chronologically, specify sublocation if needed)**:

      1. ………………………………………………………………….

      2. ………………………………………………………………….

      3. ………………………………………………………………….

**- First chamber mapping time:** Start: ………:……… Finish: ………:……… Total: ………… min

    **Second chamber mapping time:** Start: ………:……… Finish: ………:……… Total: ………… min

    **Third chamber mapping time:** Start: ………:……… Finish: ………:……… Total: ………… min

**- Total mapping time (all chambers)**: Start: ………:……… Finish: ………:……… Total: ………… min


**ABLATION DATA:**

**- Number of ablation targets (describe locations briefly):**

      1. ………………………………………………………………….

      2. ………………………………………………………………….

      3. ………………………………………………………………….

**- Number of RF applications**: ………………

**- Total RF time**: ………… sec

**- Site of origin (SOO, specify location):** …………………………………………………………………………

**- Number of points in SOO's chamber**: ………………

**- Total number of points (all chambers):** ………………

**- MAPPING SUCCESS?*:** NO /YES

**- ACUTE PROCEDURE SUCCESS**:** NO / YES

*Complete PVC abolition after NO MORE THAN 2 RF applications (< 45 seconds each) at the EAS identified using the assigned mapping approach (M vs. WF).

**Complete elimination of the PVC at the end of the procedure.

**- Total procedure time**: Start: ………:……… Finish: ………:……… Total: ………… min

**FOLLOW-UP (6 MONTHS:**

**- Date:** ........ /........ /........

**- Same morphology PVCs?:** NO / YES: ………………………………………………….

**- 24-h Holter % of PVCs:** ……………      - **24-h Holter number of PVCs:** …………………

- **Notes**:

# APPENDIX C: Proposed algorithm for prediction of right vs. left ventricular outflow tract origin of ventricular tachycardias/PVCs
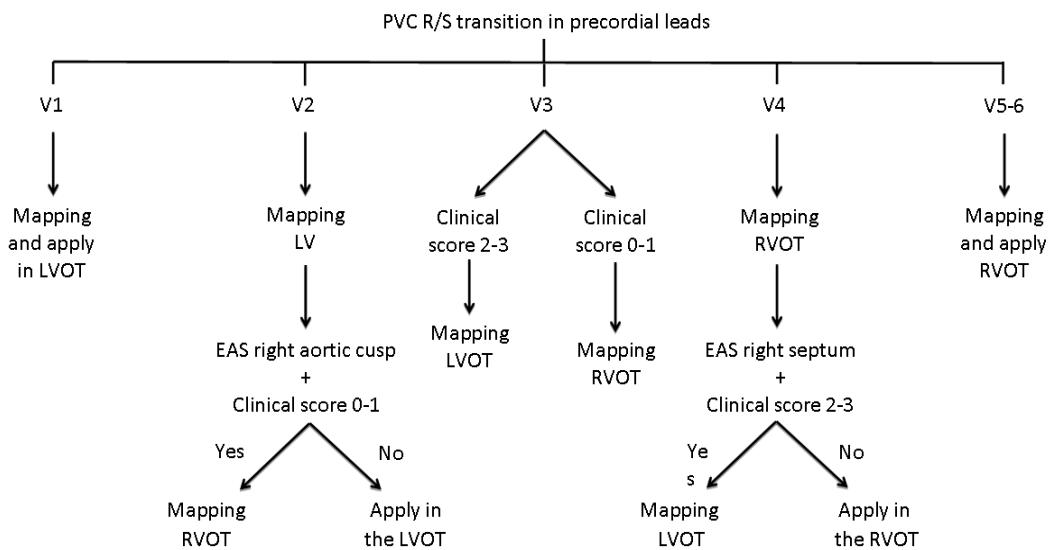


**Figure 2:** Algorithm for prediction of right vs. left ventricular outflow tract origin of ventricular tachycardias/PVCs. Clinical score[6] is obtained by summing 1 point for each of the following: hypertension, male gender, age > 50 years.