Comparative analysis of the accuracy of Smartphone Electrocardiograph D-Heart and Ambulatory 12-lead Electrocardiograph in the identification of morphological alterations of tracings of patients with Hypertrophic Cardiomyopathy

Synopsis of the Study Protocol

Rationale: In the last decade there has been an exponential increase in smartphone users and concomitantly a series of ancillary products and medical applications have been developed. However, a low-cost, user-friendly smartphone-based electrocardiograph that enables the acquisition of multiple lead Electrocardiograms (ECG), with reliability comparable to standard electrocardiograph, is still lacking. The D-Heart Electrocardiograph has been developed for iOS and Android, enabling the acquisition of surface electrical signals through 5 electrodes (3 peripheral, 2 precordials (V2-V5)) connected to a portable hardware that streams via Bluetooth the tracings to the smartphone.

Potential applications of such a are virtually unlimited, ranging from screening of populations at risk, early diagnosis of acute coronary syndromes in the territory and arrhythmias (especially developing countries), to home care / telemedicine elderly patients and / or non-mobilization.

Design and Primary Objective: Our study is a cross-sectional study with a medical device. The primary objective of the study concerns the accuracy of the

electrocardiograph D-Heart in the identification and stratification of morphological alterations of the tracings from HCM patients compared to a standard 12-lead ambulatory electrocardiograph, assuming the latter as a 'gold standard'.

Methods: Each Patient, after signing the informed consent, will receive a screening with both the D-Heart electrocardiograph that with a standard 12-lead electrocardiograph MyCardioPad Esaote (already provided for the outpatient clinic services).
Each track will be saved with an anonymous ID. The data will be viewable only by the investigators and stored in a secure database.
Two experienced observers, independent and impartial will perform data analysis.
In case where of discordance between the two observers, a third expert impartial observer would adjudicate the tracing.
To compare and quantify the magnitude of electrocardiographic changes a score will be used (previously validated by Del Cre et al. Int Journ Card 2012) based on nine criteria:
1 - Presence of a non-sinus rhythm (eg. Atrial fibrillation, atrial flutter, supraventricular tachycardia);
2 - Duration of the QRS ≥110ms;
3 - Presence of Bundle Branch Blocks (particularly Left Anterior haemiblock (LAHB), left bundle branch block (LBBB, defined as QRS> 120 ms with R broad and monophasic in DI or V5 and no Q wave in DI or V5), Right Boundle Branch Block (RBBB, defined as QRS> 120 ms with S-type 'slurred' wave in DI or V5) alone or in combination with LAHB or AVB);
4 - Abnormalities of the ST segment / T, defined as T wave inversion asymmetric ≥0.1mV in two or more leads; ST≥ segment depression of 0.1 mV to 0.08 s from j point, or negative T waves 'giants'> 10 mm in depth;
5 - ST-T segment elevation ≥ 0.2 mV;

6 - Corrected QT interval prolungation according to Bazett formula (QTc = QT / $\sqrt{\ }$ (RR)) up to 440 ms to 460 ms for men and women;

7 - Presence of pathological Q waves (definitive as Q waves with duration> 00:04 ms and depth> 3 mm);

8 - Non Q physiological wave in DI and V5;

9 - Presence of atrioventricular block of any degree.

The tracings will then be divided into 4 groups:

Group 1: normal ECG (0 criteria);

Group 2: slightly abnormal ECG (1-3 Criteria);

Group 3: Moderately abnormal ECG (4-6 Criteria);

Group 4: markedly abnormal ECG (7-9 Criteria).

Patient Selection:

Inclusion Criteria:

1) Patients with a diagnosis of Hypertrophic Cardiomyopathy

2) Achieve at least 18 or more years, with a willingness to sign the informed consent for participation in the study.

Exclusion criteria:

1) Patients who are undertaking intensive exercise (> 6 hours a week) also non-competitive.

2) Patients who do not want or are not able to sign the authorization for use and public access to the health data or informed consent.

3) Patients carriers of a pacemaker or a pacing Implantable Cardioverter Defibrillator at the time of the ECG.

Patients to enroll

The following study requires 150 patients with the diagnosis of HCM.