Empirical Evaluation of the Potential of Low-cost and Open Source "On-the-Person" ECG for Cardiopathy Pre-screening

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Abstract: Electrocardiographic (ECG) data analysis can reveal crucial information about the cardiovascular physiological phenomenon, which is modulated by the Autonomic Nervous System. Hereupon, beyond cardiovascular diagnosis, ECG markers can also reflect workload levels, or even physical and mental performance, through Heart Rate Variability (HRV) analysis. Building upon previous work found within the state-of-the-art, this pilot research explores the potential of using a low-cost device for cardiopathy pre-screening, through ECG signal analysis. With the aim of performing the rhythmical analysis, we performed empirical tests from a population of 21 control subjects in a resting position, and an additional 2 subjects, one of them in dynamic condition, in the scope of an exploratory research, using ECG wave segments analysis and HRV features extraction for numerical analysis. Results have demonstrated that the signal quality allows reliable ECG acquisition for further rhythmical and HRV analysis, in stationary and dynamic monitoring, for the bipolar leads applied. There was also evidence to suggest a benefit from including ECG morphological analysis with this hardware and software setup for prevention and diagnosis of cardiovascular disorders, although requiring further investigation.

1 INTRODUCTION

Bio-signal analysis with open source and low-cost devices has been increasingly popular in the past decades, as its applications are being recognized and extensively explored by the research and industrial engineering fields. The convergence of synergies between such diverse communities has allowed multiple enabling technologies to reach great advances in research and product development, due to the opportunity for experimentation given by the low-cost, configurability and accuracy of the current Do-it-Yourself devices. Importantly, the development of proof of concept methodologies or prototypes for bio-signal applications can represent a great cost and time reduction when compared to medical devices. They can even be further enhanced when allied to other areas with the same philosophy (i.e., low-cost enablers of new knowledge and experiences), such as 3D printing.

In the landscape of low-cost devices for biomedical applications, BITalino (http://bitalino.com/en/) has been described as a viable choice (Guerreiro et al., 2014). Beyond the hardware features, BITalino also presents a comprehensive range of software resources, within which particular attention has been given to the ECG (Silva et al., 2014, 2011; Němcová et al., 2016).

Previous research led us to further evaluate this device, aiming at reinforcing the pieces of evidence to sustain the reliability for cardiopathy pre-screening. As such, for the purpose of this study, the numerical data from the low-cost device has been empirically corroborated with the data from a gold standard device, in order to evaluate its performance. We aim to

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find evidences that support the BITalino's reliability for rhythmical and HRV parameters analysis in static and dynamic real-world applications. Furthermore, in the scope of our preliminary study, the data acquired also suggest promising results for cardiopathy detection through morphological waveform analysis.

For these purposes, a control group of 21 subjects have been monitored with BITalino, using a bipolar differential lead placement, at rest in supine position, to guarantee the same conditions that have been previously monitored by a medical team with a gold standard device. It was also included in this study the monitoring from two other subjects: in one of the subjects, namely, Subject C2, ECG waveform abnormalities were detected, as well as in one of the subjects from the control group, designated as Subject C1 and referred in Section 4.1; and the other subject, hereafter referred to as Subject C3, has performed both ECG monitoring at rest and during trail run, to perform a preliminary assessment of the behavior of BITalino in a dynamic and real-world condition.

The results from the rest monitorings point to an accurate data acquisition. Moreover, the low-cost device also shows up-and-coming results for further rhythmical and HRV parameters analysis in dynamical on-the-person ECG acquisition, as shown by the results obtained in case study 3.

2 MOTIVATION

This research builds upon a study carried out by Silva et al. (2015), where the authors described a taxonomy for the practicality of ECG devices, and performed a numerical comparison of an "off-the-person" sensor placement with a gold standard ECG device used in clinical practice. Here, we will add to this evidence by using BITalino in an "on-the-person" approach comparing its output with a gold standard medical device, and also by making a preliminary assessment of its performance in dynamic applications (as described in Section 3.1). In the range of non-invasive methods, "on-the-person" applications show consistent and continuous data acquisition once the system is attached to the body surface, allowing many different application methods. Portable devices, such as wearables (e.g., Zio TX, http:// www.irhythmtech.com/products-services/zio-xt; ActiHeart, (https://www.camntech.com/products/actiheart/ actiheart-overview) or even used within the landscape of conductive textiles (Tong et al., 2018) can have a great impact for certain age groups that require a particular approach to improve their adherence, such as children (Zhu et al., 2015) and people with disabilities.

Regarding ECG and HRV, several studies have been published using open source and low-cost tools, including BITalino-based research, revealing that the high costs of medical and state-of-the-art devices can be avoided for several applications (i.e. for proof-of-concept studies and prototyping development), due to the accuracy of such devices.

In Alves et al. (2014), BITalino's ECG performance was tested against a gold standard device — BIOPAC (https://www.biopac.com/) — aiming to introduce an electrode design for paper-based inkjet printed electrodes. With a sampling rate of 1000Hz and 10-bit resolution set up for both devices, the experimental results showed that the devices had comparable performance in Signal-to-Noise Ratio (SNR) and Root Mean Square Error (RMSE). Also, the heartbeat waveform morphology measured with BITalino and BIOPAC were very close to each other.

Silva et al. (2015) also presented a correlation of ECG data, acquired from 38 volunteers at rest, between a medical device (Philips PageWriter Trim III series) and the first version of BITalino, aiming to validate the signal acquisition accuracy for "off-the-person" applications. The medical device used a setup that included the classical 12-lead ECG placement system, whilst BITalino used a single lead, in a setup with two dry electrodes placed at the index fingers. The comparative tests showed that the "off-the-person" ECG data had a precision for R-peak detection above 98%, when compared to the corresponding lead in the gold standard device. Additionally, the segmentation performance and morphological waveform analysis showed a strong correlation between the real-world empirical data assessed for both devices, reinforcing the potential of low-cost devices.

Concerning HRV analysis, low-cost and open source tools have allowed a cost effective and multifaceted broad level of data exploitation, which is usually expensive, limited and too generic (Muñoz et al., 2017). In addition, signal post processing and HRV analysis to extract time and frequency parameters through numerical methods, allow the understanding and use of these data out of lab rooms, because their representation and physiological phenomena auto detection is supported by this approach (Tarvainen et al., 2014).

3 MATERIAL AND METHODS

3.1 Exploratory Study

In order to understand which leads would best suit the purposes of our research (i.e., future implementation in sports, stress tests, or even daily life applications), factors such as EMG noise (Levick, 2013), lead vector according to the heart's electrical conductive system (Malmivuo et al., 1995; Dubin, 2000) and lead sensitivity for ventricular events detection (Fletcher et al., 2013) were considered. Thus, bipolar Modified Chest Leads MCL_1, MCL_6, CM_5; Modified Leads I and II; and Conventional Lead (CL) (Francis, 2016; Dubin, 2000) were tested. (1) CM_5 and (2) CL leads were selected to be used in this study due to: lower EMG artifact susceptibility during limbs movement, (1) R-peak detection, explicit ventricular phenomena; (2) lead vector with approximate alignment to the heart's electrical vector for an overview perspective.

3.2 Volunteers

The study comprised a total of 21 athletes from one professional male football team, who trained twice daily. In this group the average age was 21.95±3.32 years old; the average height was 181.3±5.68 cm and the average weight was 72.3±5.81 Kg. The atheletes declared that they were not under pharmacological substance that could affect the cardiac phenomenon.

Additionally, a 34 year old female with a known family history of cardiovascular disease, referred to as subject C2, and a healthy 26 year old male, designated as subject C3 participated in the study. Results are reported in case studies 2 and 3, respectively. Subject C2 is 158 cm height and 47 Kg and subject C3 is 174 cm height and 70 Kg.

3.3 Experimental Protocol

As part of the Experimental Protocol, all the volunteers were individually informed about the procedures and aim of this study. In order to avoid any kind of external bio-electrical and electromagnetic interference, impedance issues related to the skin of the volunteers and to properly prepare the volunteers, all the procedures and ethical principles stated by Kligfield et al. (2007); Crawford et al. (1999) and the "Helsinki Declaration of Ethics" were followed. Next, the electrodes were applied in a bipolar configuration using leads CM_5 and CL.

ECG recording was performed at rest in the supine position and took place before the morning training and after lunch, before the afternoon training so that the ECG acquisition could be performed in basal conditions. Each volunteer was submitted to one ECG recording, with a minimum duration of 2 mins, according to the stated procedures in ESC/AHA (1996) for short-monitoring HRV analysis.

3.4 Acquisition Setup

3.4.1 Hardware

We used a BITalino (r)evolution Plugged Kit, with two ECG sensors, and 3D printed cases were produced to store the whole kit. The hardware set up included a BITalino (r)evolution main-board, power supplied by a 750mAh capacity and 3.7V output LiPo battery, and communication over Bluetooth to our base station — a laptop with Windows operating system.

Pre-gelled Ag/AgCl electrodes were used (see Figure 1). Table 1 presents the BITalino (r)evolution ECG sensors specifications.

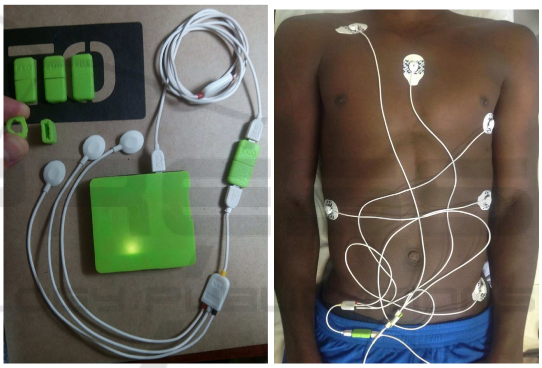

Figure 1: (left) BITalino (r)evolution Plugged Kit (mainboard and ECG sensor connected in the 3D printed cases); (right) Example of the bipolar leads electrode placement in a volunteer.

Table 1: BITalino (r)evolution ECG and BTL-08 MT PLUS specifications.

Feature	BITalino	BTL-08 MT PLUS
Sampling Rate	1000Hz	2000Hz
ADC resolution	10 bit	13 bit
Gain	1100	n.a.
Range	±1.5mV (VCC = 3.3V)	AC:±15.9 mV; DC:±400 mV
Bandwidth	0.5 — 40Hz	0.05 — 170Hz
Input Voltage Range	±1.65 V	±5 V
Input Impedance	7.5GΩ	> 20MΩ
CMRR	86dB	> 98dB

Besides our monitoring, the volunteers were submitted to ECG monitoring during the football league pre-season. This was performed using a BTL-08 MT PLUS for the standard 12-lead ECG acquisition, in rest.

3.4.2 Software

BITalino's data acquisition software was OpenSignals. The recorded data was performed at a 1000Hz sampling rate. The BTL-08 MT PLUS was set up for 2000Hz and had digital filters incorporated in the hardware — adaptable mains filter [50-60 Hz]; muscle tremor filters for 35 Hz and 25 Hz; baseline filters: 0.05 Hz (3.2 s), 0.11 Hz (1.5 s), 0.25 Hz (0.6 s), 0.50 Hz (0.3 s), 1.50 Hz (0.1 s) and splines.

The feature extraction and automatic ECG analysis for the medical device was accomplished through the BTL CARDIOPOINT ECG C600 software, for 25 mm/s and 50 mm/s recording speeds and 10 mm/s amplitude.

3.5 Data Post-processing

Although the BTL-08 MT PLUS system already provides detailed features in the generated reports, BITalino mostly performs raw data acquisition, reason for which data post-processing was needed. For raw data conversion to the correct physical units (milliVolt), the transfer function suggested in BITalino's manuals was implemented (http://bitalino.com/datasheets/REVOLUTION_ECG_Sensor_Datasheet.pdf). Further feature extraction was performed using the BioSPPy toolbox, a set of open source and Python-based routines for ECG signal filtering, R-peak detection, HR plot, waveform template (http://biosppy.readthedocs.io/en/stable/). The BioSPPy toolbox applies a band-pass filter (3-45 Hz) and also implements Christov's algorithm for QRS detection (Christov, 2004). The toolbox was adapted to obtain the standard ECG trace grid for 25mm/s recording speed and 10mm/mV amplitude, which improves rhythmical and morphological analysis by observation, as shown in Figure 2. For each subject, we have extracted ECG traces for 5 s and 10 s, as well as for complete monitoring, for raw and filtered data, and also the segmented heartbeat waveforms (Figures 4 & 8) and heart rate plots (Figure 7).

HRV feature extraction was accomplished through OpenSignals's add-on, from the raw data.

4 RESULTS

All the components of the P-QRS-T wave, segments and intervals were detectable and the R-peaks were explicit in all recorded ECG, as the example shown in Figure 4.

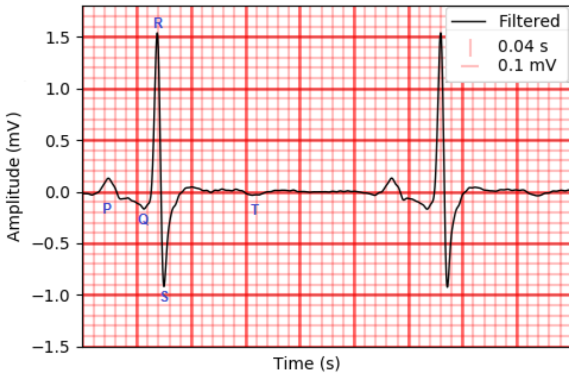

Figure 2: Portion of the ECG trace with P-QRS-T waveform identified in Subject C1 using lead CM_5 (Section 4.1, below). The inverted T wave and ECG trace grid developed are also represented. Graphical representation extracted from BioSPPy.

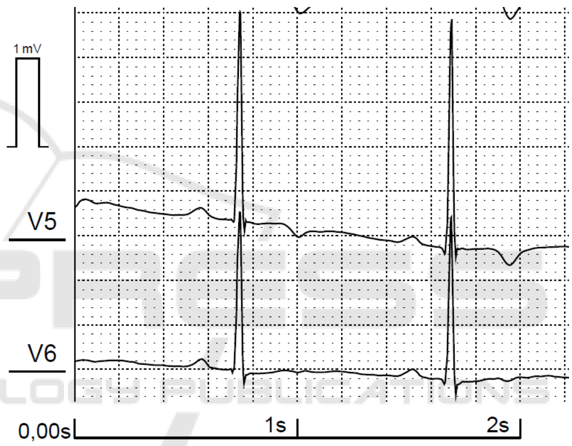

Figure 3: Portion of ECG trace for lead V_5 and V_6 recorded for Subject C1 adapted from BTL CARDIOPOINT ECG C600 reports, with a recording speed of 25 mm/s and 10 mm/mV amplitude. This portion of the ECG trace evidences the inverted T wave detected by the gold standard device.

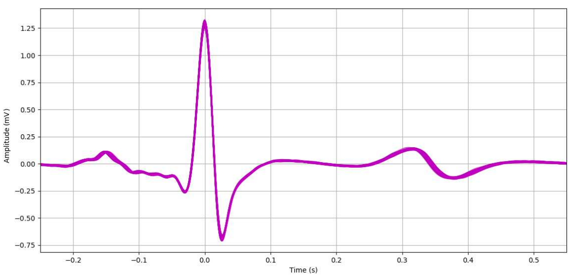

Figure 4: Example of a set of segmented heartbeat waveforms extracted from the complete ECG monitoring for Subject S20 (171.2 s), using lead CL. This graphical representation, extracted from the BioSPPy toolbox, represents the overlap of all (168) filtered P-QRS-T segments template where the absence of artifacts can be observed.

The ECG acquisition for the athletes was performed in different days, due to the time required by the hardware setup procedures that would affect atheletes training plan, as well as the medical team availability for extra days required. Although, the monitoring with the low-cost device was accomplished in following days, so the physiological condition of the volunteers could be, theoretically, similar. For these reasons, the data collected could not be synchronized between both devices. Also, the medical team only provide us the ECG reports, instead of the digital data, which has restricted the data analysis component of our work.

Nonetheless, further analysis of ECG traces from both devices, namely, the Corrected QT Interval (QTc) for the heart rate was performed for all athletes (Table 2). The lead selection for scalar absolut QT interval measurement was accomplished according to the clinical procedures for the classic 12-lead ECG, where the selected lead represents the wider QT interval within the 12 leads. We have followed the same procedure for the modified leads, acquired with BITalino. Afterwards, Bazett’s correction formula (QTc $= QT/\sqrt{\text{RR}}$ [sec]) (Postema and Wilde, 2014) was implemented to return the QTc values.

Table 2: This table presents QTc values and respective absolute QT and RR intervals, through ECG trace scalar measurement. As well as the average RR intervals for the complete monitoring of both devices, which was obtained from OpenSiganls and BTL CARDIOPOINT ECG C600 automated extraction.

Subject	BITalino (r)evolution				BTL-08 MT PLUS			
	QT (s)	RR (s)	QTc (ms)	AVG RR (ms)	QT (s)	RR (s)	QTc (ms)	AVG RR (ms)
S1	0.44	1.04	431	1052	0.4	1.4	338	1333
S2	0.44	1	440	947	0.36	0.86	388	857
S3	0.42	0.92	438	887	0.38	0.86	410	845
S4	0.44	1.04	431	973	0.44	1.12	416	1053
S5	0.48	1.46	397	1433	0.44	1.4	372	1395
S6	0.46	1.16	427	1089	0.44	1.26	392	1224
S7	0.44	1.06	427	1011	0.4	0.88	426	857
S8	0.46	1.04	451	1007	0.4	0.9	422	938
S9	0.4	0.96	408	880	0.36	0.92	375	896
S10	0.44	1.16	409	1086	0.36	0.7	430	706
S11	0.44	0.98	444	940	0.44	0.94	454	1000
S12	0.48	1.2	438	1364	0.44	1.08	423	1091
S13	0.44	1.14	412	1163	0.42	1.4	355	1395
S14	0.42	0.98	424	967	0.4	1.04	392	1000
S15	0.42	1.18	387	1008	0.38	1.32	331	1224
S16	0.44	1.56	352	1434	0.42	1.52	341	1395
S17	0.5	1.22	453	1209	0.46	1.34	397	1277
S18	0.44	1.16	409	1162	0.42	1.52	341	1463
S19	0.4	1.2	365	1029	0.38	0.96	388	938
S20	0.48	1	480	1191	0.44	1	440	1034
S21	0.52	1.44	433	1313	0.44	1.3	386	1224
AVG	0.44	1.14	427	1052	0.42	1.08	392	1053
SD	0.0306	0.172	29.55	169.5	0.0314	0.248	35.77	221.8

The following subsections describe the case studies based on ECG monitoring using BITalino, guided through the same protocol and tools as the main group of 21 volunteers, including possible cardiopathy events for the controlled group. Even though the aim of this study was to assess BITalino’s reliability for rhythmic analysis, curious evidences in wave morphology were detected and are discussed in further detail below.

4.1 Case 1 — Inverted Polarity in T Wave

In the ECG acquisition in one of the athletes, Subject C1, an abnormal waveform was detected (Figure 2). This fact was empirically corroborated using the data from the medical device, which showed that the inverted polarity of the T wave was also detected by BTL-08 MT PLUS in precordial leads V_5 and V_6 (Figure 3), but also in lead V_4. This evidence may suggest a variety of cardiac disorders, although further clinical analysis (i.e., echography) will have to be performed, to accomplish a proper diagnostic and to exclude ECG pattern alterations related to different physical activities or certain age, gender or race groups (Drezner et al., 2013; Macfarlane et al., 2014).

4.2 Case 2 — Extrasystole Detection

During the exploratory phase of this study, Lead I — an Eithoven-like setup with two electrodes placed on the wrists, for ECG monitoring in an upright seated position — has been tested in Subject C2.

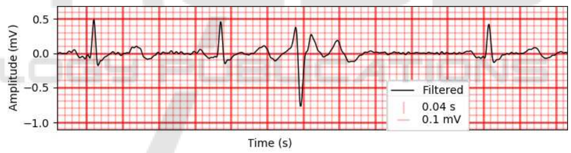

Figure 5: Portion of ECG strip showing extrasystole detected by BITalino, on Lead I, for Subject C2.

Figure 6: Extrasystole detected during the Holter exam, recorded at 25 mm/s of speed and 10 mm/mV in amplitude.

During the ECG monitoring, acquired with BITalino, abnormal events were detected and later confirmed by a trained physician, who advised the subject to be further examined at the local cardiology service. As a result, Subject C2 has performed a Holter exam — using a NovaCor device and HolterSoft Ultima V2.4.4 software — in which the medical team diagnosed extrasystoles. Afterwards, we investigated the results obtained in both tests, which can be observed in Figures 5 & 6.

4.3 Case 3 — HRV Analysis

Subject C3 performed ECG acquisition at rest and during trail running, in the scope of the exploratory phase of this study. The hardware set up was attached to the subject's clothes using a 3D printed clip, and the cables and electrodes were fixed with an elastic net tube bandage. An Android smartphone was used as the base station. Figure 7 represents the HR graph, during a portion of the trail run, which coincided with the end of the run. In Figure 8, the segmented individual heartbeat waveforms are represented for the overall run.

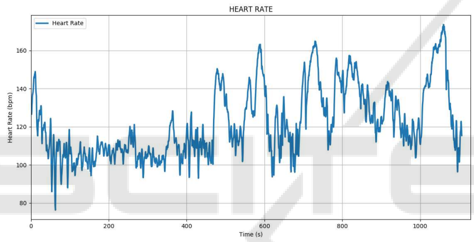

Figure 7: Portion of approximately 18 mins (1108.4 s) for HR analysis. Graph extracted through the BioSPPy toolbox for Subject C3, during a trail running.

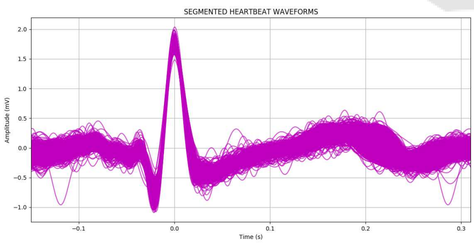

Figure 8: Segmented heartbeat waveforms for Lead CM_5 during the trail running, for approximately 18 min (1108.4 s). Signal filtered and graph generated using BioSPPy.

5 DISCUSSION

The exploratory study with Subject C3 has revealed that even under upper limbs and trunk muscles contraction, as well as in the presence of perspiration and all the evoked potentials spread by the muscular groups surrounding the electrodes, the R-peaks can be effectively detected by Lead CM_5 for long dynamic monitoring, as shown in Figures 7 & 8.

Regarding the QTc measurement, procedures found in the state-of-art and clinical practice stipulate that this measurements should be performed by using the classic 12-lead ECG analysis. However, the

Table 3: HRV time parameters extracted from CM_5 lead for Subject C3.

Time parameter	Rest	Run
Min. NN (ms)	775	344
Max. NN (ms)	937	945
Avg. NN (ms)	858	492
SD NN (ms)	30	74
rMSSD (ms)	28	21
NN20	99	389
pNN20 (%)	58	17
NN50	11	61
pNN50 (%)	6	2
Avg. IHR (BPM)	69	121
SD IHR (BPM)	2	19

Table 4: HRV non-linear parameters extracted from CM_5 lead for Subject C3.

Non-linear parameter	Rest	Run
SD1 (ms)	20	15
SD2 (ms)	39	104
SD1/SD2	0.51	0.14

Table 5: HRV frequency parameters extracted from CM_5 Lead for Subject C3.

Parameter	Rest			Run		
	VLF	LF	HF	VLF	LF	HF
Frequency (Hz)	0–0.04	0.04–0.15	0.15–0.4	0–0.04	0.04–0.15	0.15–0.4
Peak (Hz)	0.007	0.062	0.338	0.012	0.06	0.152
Power (ms^2)	122	307	300	1890	472	227
Power (%)	17	42	41	73	18	9
Power (n.u.)	–	51	49	–	68	32

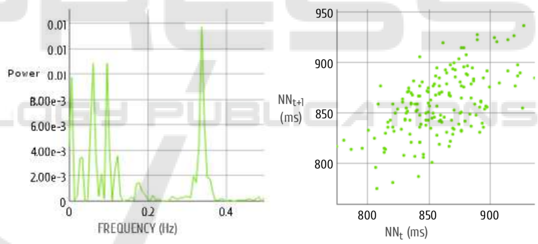

Figure 9: Power spectral density (PSD) (left) and Poincaré (right) plots for Subject C3 during rest.

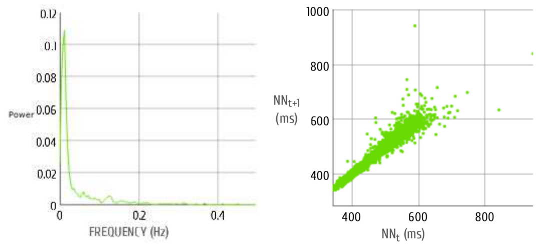

Figure 10: Power spectral density (PSD) (left) and Poincaré (right) plots for Subject C3 during trail run.

results from the modified leads show approximated values. Further investigation is needed to evaluate if a range of appropriate cut-off values allows accurate diagnosis from QTc values obtained from modified leads.

Even though there is a historical non-consensual objectivity for HRV parameters analysis (Trimmel et al., 2015), there are emerging pieces of evidence that support its use for prevention and/or monitoring of mental, physical and physiological health conditions (Hughes et al., 2010; Taelman et al., 2009), as well as in sports for physical and mental performance improvement (Peçanha et al., 2013; Dong, 2016).

HRV parameters for the control group (Table 6), the overall average values for rest acquisition suggested a good level of parasympathetic predominance. However, there were some cases that would have greatly benefited from continuous monitoring to improve the sympathovagal balance, and further physical performance improvement. It is important to note that the measures were acquired in the beginning of the football season, which meant that some of the athletes were just restarting their professional training and the physical performance was not at its peak. HRV analysis must be regular, so the data can support consistent results and avoid events that can change the physiological phenomena.

Table 6: The overall average values of HRV parameters for the control group, extracted from CL (the value of 8.1 for the LF/HF ratio is an isolated value).

	SD NN (ms)	**AVG IRH (BPM)**	**SD IHR (BPM)**	**LH / HF ratio**	**SD1/SD2**
Min.	30	41	1	0.2	0.19
Max.	162	68	7	8.1	1.13
Average	79	55	3.7	1.14	0.64

By analyzing HRV parameters in rest and during trail running (Tables 3, 4 & 5) for Subject C3, we observed the sympathetic predominance during exercise. The physical needs of the body during the aerobic exercise (i.e., oxygen absorption and carbon dioxide excretion, energy consumption, etc.) were reflected in LF predominance, besides HR increment, which increased the LF/HF ratio — PSD graphs in Figures 9 & 10 present the LF predominance during exercise.

Also, the non-linear parameters showed the same sympathovagal balance alteration. During exercise the rMSSD had also decreased, due to the decreasing parasympathetic activity. As stated by Dong (2016), we confirmed the regularity of the heart beats and sympathetic predominance during exercise, as demonstrated in the Poincaré plots in Figures 9 & 10.

6 CONCLUSIONS AND FUTURE WORK

We have presented an evaluation of a low-cost and DiY device when compared to a medical-grade system to assess the potential of the former for cardiopathy pre-screening, by performing tests in a total population of 23 subjects. Results have demonstrated that the signal quality allows reliable ECG acquisition for further rhythm and HRV analysis, in stationary and dynamic monitoring, using the bipolar leads sensor configuration. Also, we found evidence to support the use of ECG morphological analysis in prevention and diagnosis of cardiac disorders.

From a rhythmical point of view, the low-cost device has shown promising results. The case studies discussed and the results obtained also motivated our team to investigate BITalino’s potential consistency for abnormal waveform pattern detection in severe pathologies and demanding environmental conditions, towards its maximum usability for rhythmical and morphological ECG analysis.

In the future, we aim to further test the reliability of BITalino to monitor subjects with diagnosed rhythmical cardiac disorders, both during rest and stress tests. Patients will be monitored with a synchronized gold standard device, in order to assess the accuracy that can be achieved with BITalino. We will evaluate the rhythmical analysis, including HRV for continuous monitoring, and wave morphology analysis in this context. With the synchronized acquisition setup, we will also be able to determine whether a cut-off value can be set for QTc measurement accuracy with modified leads. In addition, other bipolar leads will be explored to attain different electrical lead vectors, so the analysis of the heart atria can be improved, as well as new approaches for LF/HF ratio analysis that can better track mental and emotional states, in a similar fashion to the method developed by von Rosenberg et al. (2017).

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