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The Heart Sentinel™ app for detection and automatic alerting in cardiac arrest during outdoor sports: Field tests and ventricular fibrillation simulation results

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ABSTRACT

Introduction: The Heart Sentinel™ app (HS-app) is conceived to detect cardiac arrest during outdoor sports, automatically alerting contacts via SMS with GPS position data. It automatically starts the chain of survival in case no bystander has witnessed the event, using commercially-available chest strap heart monitor and a smartphone. The heart rate analysis arm of the algorithm is extremely sensitive, with specificity being addressed by motion analysis through smartphone sensors, since only unexpected prolonged absence of motion would confirm true cardiac arrest and start an alert code.

We assessed the accuracy of such HS-app with simulated exercise-associated ventricular fibrillation (VF), and possible false positives in real-world athletes.

Methods: The occurrence of false positive alerts was tested in the outdoor field, through athletes regularly running and cycling, and with ECG simulators.

The occurrence of false negatives for VF detection was assessed with 3 different ECG simulators, using VF simulation protocols.

Results: The false positive initiation of an alert countdown was recorded twice during 829 h of outdoor sports. Both athletes were able to stop such false positive 15-second countdown before the alert SMS was dispatched. No false positive SMS was dispatched. False negatives were not recorded under any simulation protocol.

Conclusion: A simple smartphone app, using commercially-available heart rate monitors, is promising to detect cardiac arrest caused by VF during sports, triggering automatic dispatch of emergency SMS with GPS position. During outdoor exercise, HS-app would be helpful for cases of exercise-associated cardiac arrest.

1. Introduction

A multitude of athletes, typically joggers, long-distance runners or bikers, use to practice alone in the countryside or other non-crowded settings where an exercise-associated cardiac arrest (EACA) is typically not witnessed, due to the absence of bystanders. The lack of a quick emergency alert, starting the chain of survival, is in this case the key limiting factor to early defibrillation access, which could reduce morbidity and mortality in such rare and unexpected dismal events. The better survival rate of EACA compared with similar events not related to exercise has been described as the consequence of cardiac arrest being more often witnessed when taking place in sport facilities; a potential new approach to specifically improve outdoor sports safety remains desirable [1]. Warning signs are not infrequent before EACA takes place, so that monitoring exercise in such higher risk patients could be especially useful [2]. Today most athletes practice outdoor sports carrying a smartphone with them. Heart Sentinel™ app (HS-app), previously known as the Parachute-app (Phone App for Rapid ACtion in Human Unconsciousness Threat during Exercise) [3,4] is the first smartphone app designed to automatically detect the high probability that the subject is experiencing EACA during outdoor sports. It automatically proceeds to alert pre-defined emergency contacts through multiple SMS including GPS coordinates to drive rescuers to the cardiac arrest scene. This automatic alert of close relatives and friends can translate into quick activation of the chain of survival on behalf of the incapacitated

Abbreviations: HS-app, Heart Sentinel™ smartphone application; VF, Ventricular fibrillation; EACA, Exercise-associated cardiac arrest; HR, Heart rate; SMS, Short message service; BLE, Bluetooth low-energy; GPS, Global positioning system.

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subject when no bystander is available, which would hopefully lead to rescue defibrillation within the shortest possible time. HS-app takes advantage of non-medical, non-proprietary and commercially-available sports equipment, which may favor widespread use: 1) a low-energy Bluetooth low-energy (BLE) heart monitor (either a standard chest-strap type heart monitor or a sensor infused wearable T-shirt), and 2) a smartphone (or a "watchphone") running the HS-app.

HS-app continuously monitors heart rate (HR) through the HR monitor and detects abnormally irregular HR behavior associated with life-threatening arrhythmias such as ventricular fibrillation (VF), thanks to its patent-pending HR analysis algorithm. Since the HS-app HR algorithm is extremely sensitive to several types of arrhythmias, but not necessarily specific for life-threatening pulseless arrhythmias (it may not reliably differentiate VF from more benign supraventricular arrhythmias) the unique intuition is to combine HR analysis with a second arm in the HS-app algorithm, i.e. continuous motion analysis through smartphone sensors, which is able to classify as false positive any HR-based "red flag" which is not confirmed as a pulseless arrhythmia by lack of association with prolonged absence of motion (by definition associated with true cardiac arrest). Only if *both* the HR-based analysis arm and the absence of motion arm of the algorithm indicate "red flags" concurrently, the HS-app then presents a consciousness-check to the subject, in the form of a 15-second countdown, after which, if not interrupted, emergency SMS with GPS location data (to predefined contacts) are finally sent by the smartphone. (Fig. 1) The current study sought to assess a) the potential *false negative rate* of the HS-app for the detection of simulated EACA due to VF, using ECG arrhythmia simulators and b) the potential *false positive detection rate* for EACA when simulating normal exercise ECG and additionally testing the HS-app in athletes during real-life outdoor sports.

2. Methods

2.1. How the HS-app works

The HS-app is a smartphone app running on both iOS and Android operative system smartphones, which continuously monitors HR data transmitted wireless in real-time by commercially-available BLE heart rate monitors, at a frequency of 1 value per second. In the current study we used Apple iPhone models 5, 5s or 6 running iOS 9. Such HR monitors, which operate by sensing cardiac electrical activity, are inherently more reliable than more recently available optical/plethysmographic sensors, which rely on much less robust peripheral pulse detection. They sense electrical heart activity through two poles (bipolar single lead) in contact with the skin, few centimeters right and left of the lower sternum, and they convey cardiac electrical activity to a small core device for filtering, digital conversion and BLE transmission; HR sensors may be configured as standard chest-strap type, or equivalent wearable alternatives embedding the electrical poles (and BLE transmitter) in a t-shirt or bra. In the current study both a standard chest-strap BLE HR monitor (Wahoo Tickr) and a t-shirt type (Sensoria inc) were tested. The HS-app applies a patent-pending algorithm, previously known under the "Parachute-app" name; under that name its concept and preliminary data have been presented at 2016 cardiology meetings [3,4]. The algorithm and the app itself will be commercially available from now on only under the newly-registered Heart-Sentinel™ name, but the diagnostic algorithm remains the exactly the same of the Parachute app, since only the user-interface was modified.

Such diagnostic algorithm is continuously applied to the HR data received in real-time by the smartphone (one HR value per second) to screen for two specific key abnormalities in the HR data sequence, which we have found to strictly associate with the initiation or presence of VF in our pilot arrhythmia simulations, compared with normal outdoor exercise in healthy subjects using HR monitors. Such abnormalities are defined as the presence of at least one of two apparently "opposite" markers: either a) abnormal extreme irregularity of sensed contiguous HR data points or b) abnormal constancy of sensed contiguous HR data points (details of the algorithm cannot be disclosed due to patent-pending), both representing non-physiological HR behavior specifically during the exercise period, but also during resting.

2.2. ECG simulation setup (Fig. 2, see also Appendix Video 1)

The simulation system consisted of a 12 lead ECG arrhythmia simulator, wired both to the chest strap HR monitor poles (or T-shirt poles in case of wearable garment HR

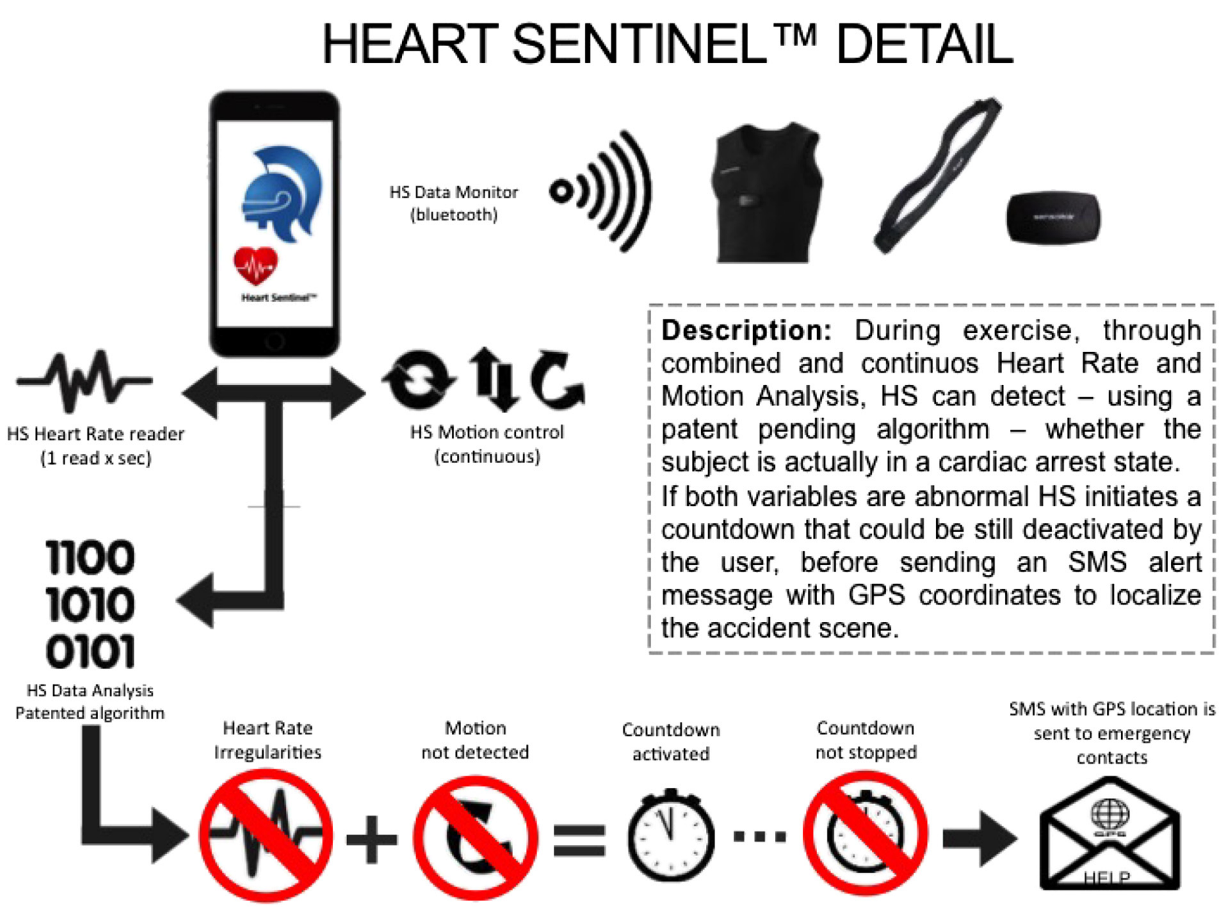

Fig. 1. Heart Sentinel™ mechanism. Only in case both arms of the algorithm -heart rate and motion monitoring- do sense abnormal data the final countdown to sending SMS alerts is activated.

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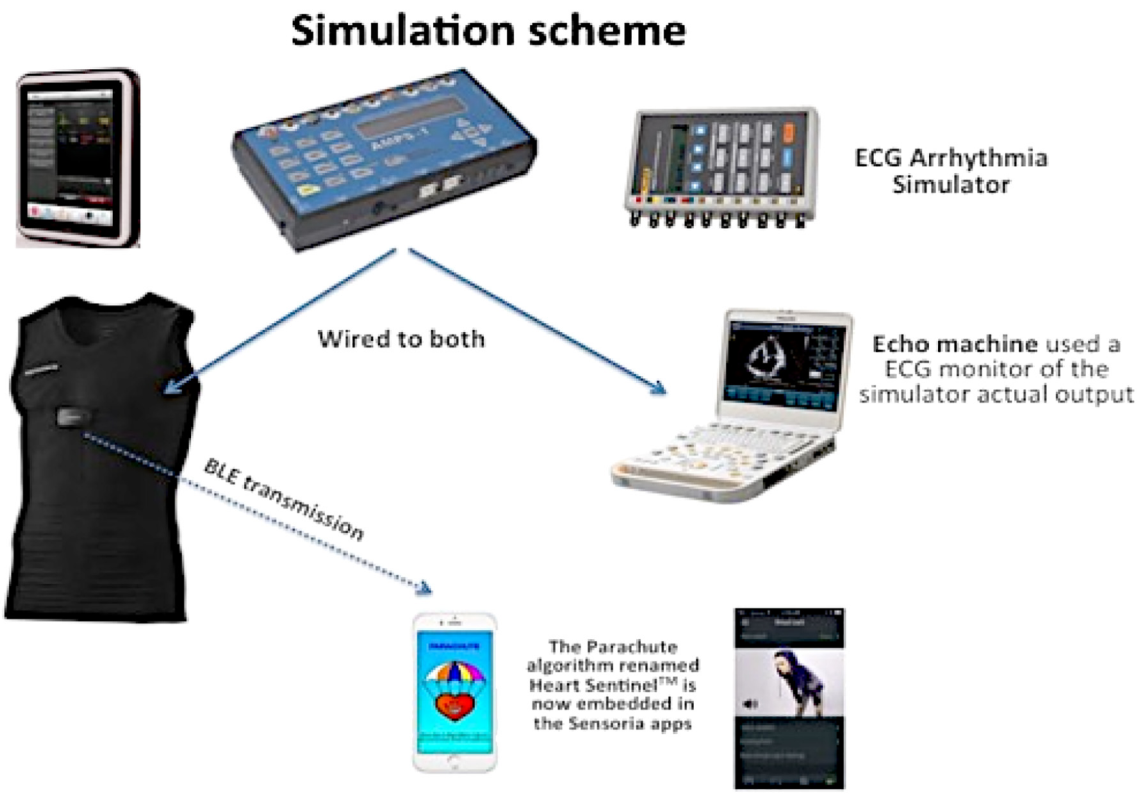

Fig. 2. Laerdal Simpad, AMPS1 and Fluke PS420 simulators (from left to right in the upper part) were sequentially tested with Heart Sentinel™ app using this testlab configuration.

monitor) and in parallel to an ECG monitor (3-electrode ECG module of Philips Cx50 echocardiograph) to demonstrate the simulated ECG tracings in real-time. The simulator leads LA and LL (any arm lead combined with any leg lead is also appropriate) were respectively wired to right and left pole of the chest heart monitor, while simulator leads RA, RL and V6 (other combinations of 3 appropriate leads are equivalent) were wired to the abovementioned ECG module to display the real-time simulator output.

In this simulation scheme a) the simulator hardware outputs a programmable ECG tracing, b) sensed by the chest strap HR monitor, which finally c) sends HR data (via BLE) in real-time to the receiving smartphone running the HS-app. For all conducted VF simulations the primary endpoint was the capability of HS-app to detect simulated VF producing the alert countdown audio/visual output (binary yes/no) and, as a secondary endpoint, the time needed to receive the cardiac arrest emergency alert SMS (sent 15 s after the start of the countdown) using a second receiving smartphone previously indicated in the HS-app as the emergency contact. Such secondary endpoint also tests carrier-dependent time to SMS actual delivery.

2.3. Study design and testing protocol

We tested the occurrence of false positive alerts during a) real-life normal exercise and during b) simulated exercise as follows:

a) in the outdoor, by means of 30 voluntary athletes running and cycling at least twice a week for one month, wearing the HR monitors (15 used the chest strap HR monitor and 15 the t-shirt HR monitor).
b) with 3 different ECG simulators (Fluke PS420, AMPS1, Laerdal SimPad), set both at standard 1 mV and halved 0.5 mV output, starting from normal sinus rhythm and changing progressively to sinus tachycardia, continuously varying HR up to 190/min and down to 50/min, back and forth for 5-min tests each, to reproduce normal HR accelerations and decelerations during exercise. The rate of HR change in time, which is key and may influence the detection accuracy of the HR arm of the algorithm, was varied between a minimum of 0 beats variation in consecutive HR data (i.e. keeping the same sharp HR for up to 15 s) and a maximum variation of 5 beats per second (a change in two contiguous HR data points of 5 beats). We obtained such reference HR variation range from data collected in healthy runners (unpublished data, Fig. 3a and b and see also Appendix Video 2) in whom both a) the same repetitive HR value was physiologically never recorded for more than 11 consequent HR readings and, at the opposite, b) maximal delta between two consecutive HR readings (during maximal acceleration or deceleration) was never more than 5 beats. Although rest condition is not the setting during which the HS algorithm is going to be applied, due to active motion being a key component of the full algorithm, we also tested HR behavior in the supine resting subject in our pilot data collection. As expected, longer sequences of consecutive superimposable HR values were recorded during rest compared with exercise, although, still, the longest repetitive series never exceeded 14 values (or seconds, since HR is received at 1 value per second rate). (see also Appendix Video 3 and Fig. A).

During ECG simulations the movement associated with normal exercise was simulated by manually keeping the smartphone always in light and continuous motion.

The potential occurrence of false negatives alerts (defined as an alert countdown not starting within 1 min from start of VF simulation) was tested with the 3 abovementioned ECG arrhythmia simulators, and was performed 5 times for each sequence available in each simulator and for each of the 2 HR monitors (140 overall VF simulation sequences performed). Details of the different types of VF sequences are reported in the online Appendix, which also reports links to videos 4 and 5 demonstrating paradigmatic examples of VF tests, as they were conducted.

The simulation of a sudden VF rapidly causing an unconsciousness/incapacitating state during exercise was conducted, as far as motion simulation is concerned, simply stopping the smartphone (which was instead kept in light and continuous motion before the simulated arrhythmia start) by laying it still on a table 10 s after VF simulation was started, a time-lag considered adequate for loss of consciousness after VF start.

2.4. Statistical analysis

Basic descriptive statistics was used, and VF test results were simply tabulated.

3. Results

The 30 voluntary athletes were 17 males and 13 females. They have run and biked for overall 829 h during the study. Mean age was 39.1 $\pm$ 8.1 y/o. The false positive initiation of the 15-s alert countdown to emergency SMS sending (which can be manually stopped) was recorded twice during the overall 829 h of outdoor sports tests. In both cases the false start of the pre-alert countdown took place during temporary resting of the athlete during their practice session, lying down supine taking some rest. They reported to have detached the smartphone from the armband for a phone call without pausing the HS-app, as suggested by the app itself when sensing prolonged absence of motion with a normal HR behavior), and they manipulated the chest strap/t-shirt sensor because felt uncomfortable during that relaxation time. One athlete was wearing the chest strap and one the t-shirt. Both athletes were

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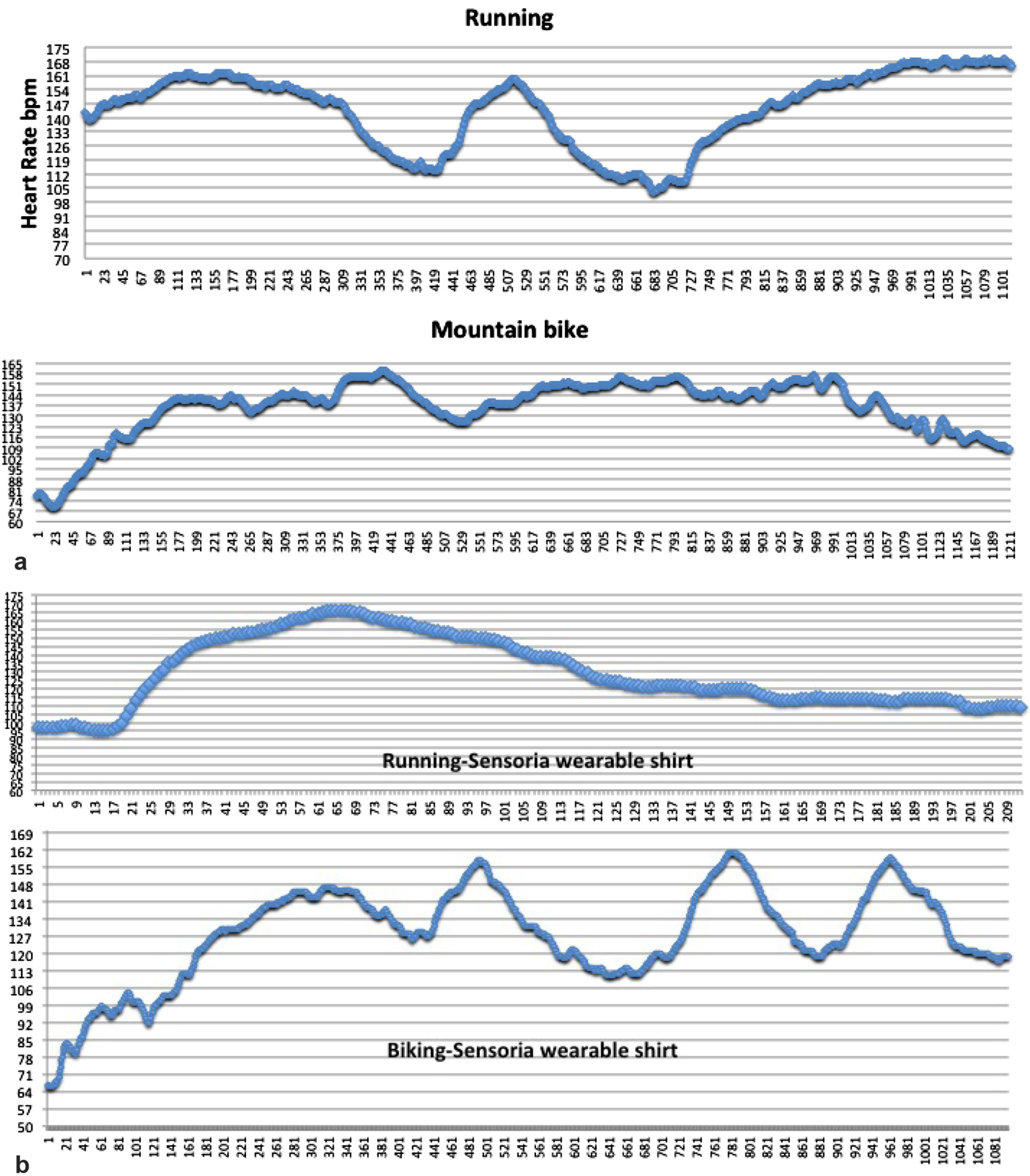

Fig. 3. a shows a typical running and biking heart rate graph obtained with Wahoo tickr chest-strap heart rate monitor. On the y-axis heart rate (beats/min) at one value per second and time on the x-axis (seconds). No consecutive heart rate variation in these examples exceeds 3 beats/s. b shows a typical running and biking heart rate graph obtained with Sensoria wearable heart rate monitor. On the y-axis heart rate (beats/min) at one value per second and time on the x-axis (seconds). No beat-to-beat heart rate variation ever in these examples exceeds 5 beats/s.

able to abort the false positive outgoing SMS emergency alert during the 15-second countdown, so that finally no SMS was actually sent to emergency contacts. The false positive rate can be described as 2 alert countdowns out of 829 h of outdoor exercise, but 0 emergency SMS sent.

The occurrence of false negatives was tested using the 140 overall sequences of VF simulation which resulted in a 100% VF detection rate (140/140) using all simulators and protocols (Fig. 4a and b and online Appendix Videos 4 and 5).

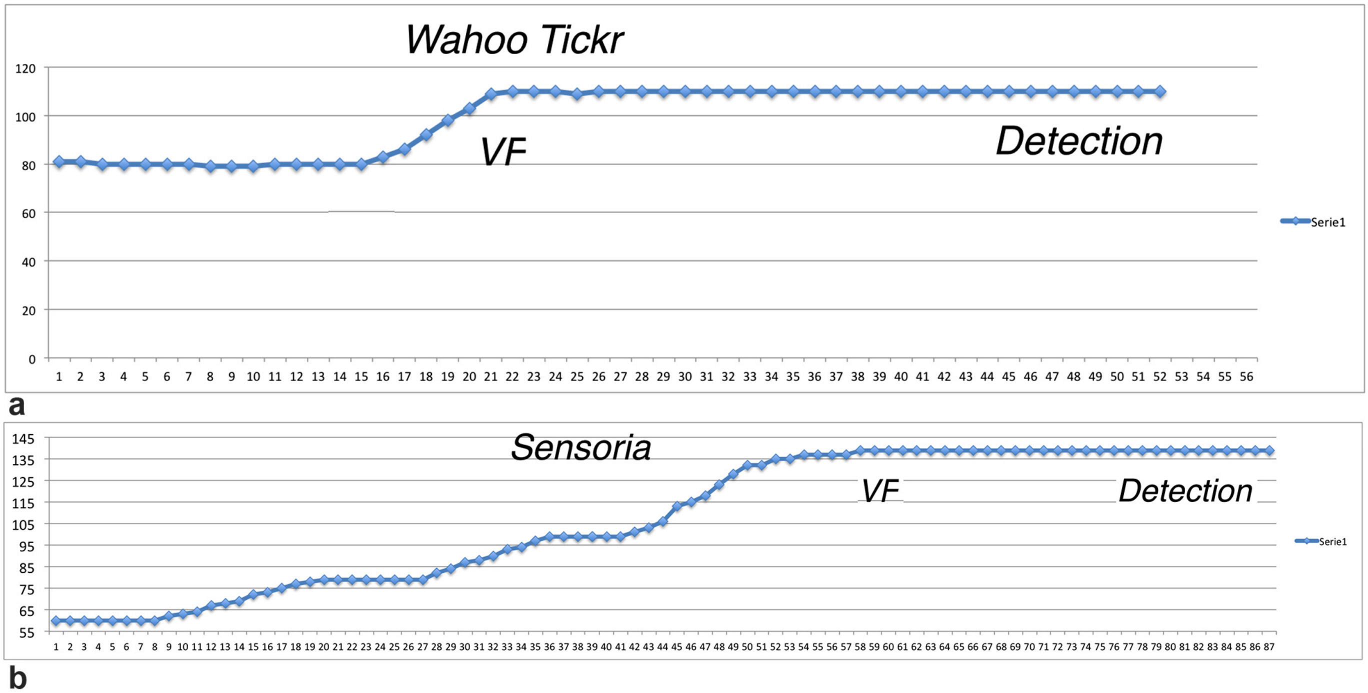

Fig. 4. a Simulation of ventricular fibrillation (VF) starting after normal sinus rhythm, which is only mildly increased to sinus tachycardia 110 beats/min as to approximate initial phase of exercise. Wahoo chest-strap monitor reacts by stucking at prior 100 beats/min value, repeating the same value until the HS-app recognizes such long repetition sequence. b Simulation of ventricular fibrillation (VF) starting after normal sinus rhythm progressively increased to sinus tachycardia up to 140 beats/min as to approximate exercise. Sensoria wearable t-shirt heart rate monitor reacts by stucking at prior 140/min value, repeating the value until the HS-app recognizes such long repetition sequence.

3.1. Secondary endpoint

Time from VF start to SMS delivery to the selected emergency number was 54 ± 5 s. Time from VF to countdown start was almost superimposable, predictably 30 s sharp, since the HR arm of the algorithm takes 25 s as a minimum for VF detection, but in parallel 30 s were per-protocol required by the absence of motion arm of the algorithm (20 s are programmed as the minimum required time to define prolonged absence of motion, and the smartphone light continuous motion was per-protocol stopped 10 s after VF start). Since countdown is15 seconds, 45 (30 + 15) seconds was the expected uncompressible time, while network time to deliver SMS was an independent variable, ranging from few seconds up to 20 s in our tests.

4. Discussion

In the current study we demonstrate that the HS-app is an accurate method of detection of simulated VF during outdoor sports, in the given testing conditions, and the use of such an app during real-life outdoor sports coupled with commercially-available HR monitors is safe and does not dispatch false SMS alerts. The HS-app, as most useful solutions addressing clinical issues, is simple in its concept and in its hardware, since chest strap-type HR monitors and smartphones have been available for many years now and they are not per-se classified as medical devices. Nonetheless, the HS-app might fall under the medical app category and for this reason the HS-app is undergoing FDA pre-submission evaluation, for assessment and possible clearance.

Few considerations are usually raised regarding the HS-app:

a) *EACA is a very rare event*, so that it may not be worth priority. While the incidence of EACA is apparently as low as 1/100000 athletes/year, that would nonetheless translate in a non-trivial number of victims, around 2400 subjects in US only, and most of them are middle-age socially active adults.
b) *EACA takes place in sports arenas or gyms.* Events taking place during team-sports are prevalent, although a minor but significant proportion of EACA strike athletes running or cycling in the outdoor in the absence of bystanders, but that percentage (10–20%?) would still account for a significant number of events addressable by the HS-app (n = 240–480 in US only) if it were widely diffused among all athletes, at the low-cost of a smartphone app (predictably few dollars a year), a negligible cost for athletes, used to very costly devices and garments.
c) *To prevent through screening is better than rescue and would better solve the EACA problem.* Post-mortem evidence [1] reports that 60% of sudden cardiac death in athletes takes place during sports (40% during rest/sleep). Underlying causes are not identifiable at post-mortem (normal heart) in more than 40% of cases (sudden arrhythmic death syndrome) while almost 20% are classified as having left ventricle idiopathic non-ischemic fibrosis, also not identifiable by screening programs. It appears that, even if screening programs remain somewhat useful, no preventive strategy will ever be able to identify the majority of subjects at risk for EACA and a "secondary prevention" strategy of active monitoring and alerting during exercise may be key to try and rescue at least a portion of subjects with such unpredictable events [5].
d) *EACA have a higher survival rate than cardiac arrests during rest.* This is true only as far as EACA take place in sports facilities, while EACA outside sports facilities are apparently as deadly as the ones not associated with exercise. [6]
e) *Quick Alert does not mean quick rescue.* Not all subjects undergoing an EACA will be saved even if HS-app would rapidly alert family and friends in 100% of cases, since the time needed to bring an emergency rescue team with a defibrillator to the EACA scene may sometimes exceed the time limit for successful rescue.
Nonetheless, in several sudden cardiac death studies, such as the Oregon Sudden Unexpected Death Study (Oregon-SUDS) [7] the mean time to defibrillation is between 6 and 7 min, and while it is conceivable that in remote outdoor settings the time needed will often exceed that interval, in many cases that would not be the case. It is obvious that we are not definitely and fully solving a complex problem such as EACA, often arising from unknown but not

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always fully asymptomatic coronary artery disease [8,9], but while we are rightly using helmets, safety belts and airbags to address deadly consequences of traumas, we are not expecting they are always successful in saving lives: the same applies to HS-app for EACA. Further, it might be interesting to integrate the HS-app with widely diffused crowd-resuscitation apps (Pulsepoint app and alike) to possibly buy more time for rescue defibrillation, automatically alerting nearby rescuers to rush to the scene and perform basic life support before rescue defibrillation is finally available.

f) *The HS-app needs network cellular signal for SMS dispatching*, and the absence of network signal would force the HS-app in a standby condition, a condition the user is readily advised of, with automatic restart when signal comes back, but the subject is not protected for that limited period of time of signal absence. Today most of the industrial world has a very high percentage of its territory covered by cellular networks, which is further steadily increasing month by month.

4.1. Study limitations

It was not feasible to test HS-app capability to detect VF in spontaneous real-life EACA, due to the rarity of such unpredictable event in healthy sportsmen and sportswomen, and the induction of VF in human beings during electrophysiology studies was also perceived as arguably ethical. Furthermore, such artificially provoked VF is triggered during electrophysiology tests using appropriately timed intracardiac electrical stimuli/DC shocks, which would be sensed and would unpredictably interact with HR monitors worn by the subject, making this type of simulation setting remarkably different from real-life spontaneous VF.

We tested VF in this study, since it is recognized as the most frequent arrhythmic cause of cardiac arrest, although the HS-app also detects as "red flag" most arrhythmias through its HR analysis algorithm, but such rhythms (VT or asystole) were not specifically tested in the current study.

Bluetooth HR monitors are produced by many vendors, but we tested only two commercially-available models. Results of the current study should not be extrapolated to untested HR monitors. Heart rate monitors using peripheral pulse sensors were not tested, since conceptually unfit, not being based on electrical cardiac activity, as instead required by the HS-app.

5. Conclusions

A smartphone app used in conjunction with a simple BLE chest strap or wearable t-shirt/bra heart monitor is potentially accurate and a very promising new tool to detect EACA and start an emergency alert through multiple SMS reporting GPS position, favoring a quick start of emergency rescue in the outdoor, when the absence of bystanders would preclude the start of an emergency call at all.

Conflict of interest

Dr. Gaibazzi and Dr. Reverberi are cofounders of the Parachute-app srls company, which owns the Heart Sentinel™ app license and patents applications.

Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.ijcard.2018.07.062.

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