

Feasibility of evaluation of Polar H10 chest-belt ECG in patients with a broad range of heart conditions

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ARTICLE INFO

Article history:

Submitted: 15. 7. 2022

Accepted: 15. 7. 2022

Available online: 25. 7. 2022

Klíčová slova:

Artefakty

Fibrilace síní

Hrudní pás

Nástroje pro screening arytmií

Polar H10

SOUHRN

Úvod: Hrudní pás umožňuje pořídit 1svodový EKG záznam. Získaná data byla validována pro měření srdeční frekvence a rovněž i pro detekci fibrilace síní díky srovnání s krátkými EKG záznamy z holterovského EKG měření u selektovaných pacientů. Zatím ale nebyla ověřena možnost vyhodnocení dlouhých EKG záznamů u neselektovaných kardiologických pacientů se širokým spektrem srdečních chorob.

Metodologie a výsledky: Do studie bylo zařazeno 54 hospitalizovaných a 53 ambulantních pacientů a 54 zdravých kontrol (n = 161 celkově). U všech účastníků studie byl pomocí hrudního pásu Polar H10 pořízen 1–2hodinový EKG záznam (celkově 1 153 229 úderů srdce; průměrná srdeční frekvence 76,6/min; sinusový rytmus u 86,3 %, fibrilace síní zjištěna u 13,7 %; dokumentováno 0,46 % síňových extrasystol a 0,49 % komorových extrasystol). Z výše uvedeného počtu 1 153 229 srdečních tepů jich 1 128 319 bylo hodnoceno lékařem jako snadno interpretovatelných. Celkově tak bylo 2,16 % záznamu vyhodnoceno jako obtížně interpretovatelný nebo neinterpretovatelný šum (A: 2,31 %; B: 1,95 %; C: 2,20 %). Z EKG záznamu z hrudního pásu lékař při srovnání s 12svodovým EKG záznamem spolehlivě určil základní srdeční rytmus u většiny účastníků (u 51/54 [94,4 %] hospitalizovaných pacientů a u 100 % ambulantních pacientů a zdravých kontrol). U tří jedinců byl základní rytmus na EKG vyhodnocen jako nejasný. U všech tří byly všechny komplexy QRS stimulované. U hospitalizovaných pacientů byl EKG záznam z hrudního pásu zobrazený v reálném čase na mobilním telefonu srovnatelný s EKG záznamem z telemetrického monitorování (shoda v 53 z 54 případů; 98,1 %).

Závěr: EKG záznam z hrudního pásu, pořízený u hospitalizovaných i ambulantních pacientů s různými typy poruch srdečního rytmu, stejně tak jako u zdravých kontrol, lze v každodenní praxi použít pro zhodnocení základního srdečního rytmu, záchyt fibrilace síní i extrasystol, a to při minimálním procentu obtížně hodnotitelných záznamů. Opatrnosti je třeba při interpretaci EKG záznamu u pacientů se stimulovaným rytmem a u pacientů s flutterem síní. Hrudní pás je tak možno použít pro kontinuální EKG monitorování, hodnocení srdečního rytmu i screening fibrilace síní.

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ABSTRACT

Background: The chest-belt can be used to obtain a 1-lead ECG. Data from it have been validated for the determination of heart rate and for the possibility to detect atrial fibrillation (AF) compared to ECG-Holter on a short ECG recording in selected patients. However, validation of the possibility to evaluate long ECG recordings in patients with a wide range of heart diseases has not yet been performed.

Methodology and results: 54 hospitalized patients, 53 outpatients and 54 healthy controls were enrolled in the study (n = 161 in total). Using a Polar H10 chest-belt, 1–2 hours of ECG were recorded in all patients (1 153 229 heartbeats, average heart rate 76.6/min, 86.3% in sinus rhythm, 13.7% with atrial fibrillation, 0.46% atrial premature beats, 0.49% ventricular premature beats). The presence of noise was 2.16% (A: 2.31%; B: 1.95%; C: 2.20%). 1 128 319 / 1 153 229 were evaluated as easy to interpret. Using ECG from the belt, the basic rhythm was reliably determined by the physician in majority of patients (51/54, 94.4% in hospitalized patients; in 100% of outpatients and healthy controls) when compared to 12-lead ECG. 3 cases were evaluated as unclear; in all of these cases, all QRS complexes were stimulated by a pacemaker. In hospitalized patients, real-time ECG from the belt was comparable to telemetric ECG monitoring (match in 53/54, 98.1%).

Conclusion: The ECG obtained from the chest-belt in hospitalized patients and outpatients with a wide range of cardiovascular diseases, as well as in healthy individuals, is usable in real practice for evaluation of baseline rhythm, atrial fibrillation and premature contractions with a minimal proportion of difficulties to interpret recordings due to artefacts. Caution should be exercised in interpretation of the ECG in patients with stimulated rhythm and in patients with atrial flutter. The chest belt can be used as a means for continuous monitoring of ECG, evaluation of rhythm and screening of atrial fibrillation.

Keywords:

Atrial fibrillation

Chest-belt

Noise

Polar H10

Screening tools

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DOI: 10.33678/cor.2022.083

Background

Cardiovascular diseases (CVDs) are one of the most common causes of death in general. According to the WHO, 17.9 million people die from CVDs every year, corresponding to 32% of all deaths.¹ Arrhythmias belong among the most serious CVDs associated with significant morbidity and mortality.² The most common arrhythmia in adults is atrial fibrillation (AF). Currently, the prevalence of AF is estimated to be 2–4%.³ However, due to the ageing population and the increased efforts to diagnose AF in recent years, a significant (2.3-fold) increase can be expected.⁴ AF-related symptoms may be disabling, but a significant proportion of patients have little or no difficulty.⁵ The high cost of treating AF leads to the development of strategies to identify and treat previously undiagnosed AF patients. The right choice of screening tools is important. By convention, to diagnose AF, an episode lasting at least 30 seconds is needed.⁶ Longer monitoring logically leads to greater arrhythmia detection, but systematic screening is significantly more costly than opportunistic screening.⁷ Implantable recorders and devices can lead to detection of a number of subclinical AF episodes and atrial high-rate episodes (AHRE) through continuous recording.⁸ Implantable recorders are rarely available, costly, and invasive to implant. However, detection of asymptomatic AF by non-invasive recorders is significantly less likely due to the short duration of recordings.⁹ Holter-ECG is the standard for monitoring. Its use is opportunistic and is associated with a number of logistical hurdles, so it cannot be available to all patients for a long period of time or precisely at the time of any symptoms. Instruments using a photoplethysmography (PPG) sensor may record heart rate (HR) continuously, but their accuracy is very limited and they are associated with numerous artefacts.¹⁰ ECG-capable devices such as Apple iWatch, AliveCor etc. can be very useful in real life for symptoms verification or occasional screening, but their use is limited for longer recordings and detection of asymptomatic episodes.^{11,12} The chest-belt can be used to obtain a 1-lead ECG. In general, the data from it have so far been used to determine HR and heart rate variability (HRV). However, unlike PPG-based devices, these devices have been designed to be used in sub-optimal conditions. The quality of the evaluation of RR intervals (RRI) has been sufficiently validated.^{13,14} Similarly, the accuracy of the detection of AF compared to the ECG-Holter on a shorter ECG record in selected patients has been validated.¹⁵ The chest-belt could be the optimal screening tool for AF detection, considering the possibility to use it anywhere, anytime, under real, sub-optimal conditions. However, validation of the possibility to evaluate all beats in long ECG recordings from the chest-belt in patients with a wide range of cardiovascular diseases (CVDs) under real-life conditions has not yet been performed.

Study design

To confirm the possibility of ECG evaluation in patients with a wide spectrum of CVDs under real-life conditions,

we designed a prospective, non-randomized study in which three groups of patients were evaluated:

Group A – hospitalized patients.

Group B – patients from arrhythmology outpatient department.

Group C – healthy individuals without a prior diagnosis of a CVD.

The aim was to verify the possibility of evaluation and correct assessment of all heart beats on a long 1-lead ECG by an experienced cardiologist in patients with different body types, weight, height, BMI, with different rhythms, different heart rate, with the presence of bundle branch block, pacemaker, cardioverter-defibrillator, stimulated rhythm. In general, in unselected hospitalized patients in a large cardiology department in a university hospital, in patients in arrhythmia outpatient department and in healthy controls for comparison.

A separate objective was to evaluate the real presence of artefacts, or noise, respectively, preventing ECG evaluation in individual groups of patients.

Patient group

The aim was to evaluate more than 1 million heartbeats from longer records lasting 1–2 hours in each consecutive patient.

With an estimated average heart rate of 70/min and an average measurement time of 90 minutes, 160 patients were predicted to be enrolled in the trial.

The study protocol was approved by the Palacky University Multicenter Ethics Committee (reference number: 54/22).

Inclusion criteria

Age >18 years. Willingness to cooperate and signing of an informed consent (ICF) with the study.

Inclusion criteria specific for individual subgroups:

Group A: Hospitalization. At least 1 known CVD. Telemetry actively used at the time of acquisition of ECG using the chest-belt. Possibility of 12-lead ECG measurement.

Group B: Elective visit in an arrhythmology outpatient department. Previously established diagnosis of arrhythmia or suspected arrhythmia by symptoms. Possibility of 12-lead ECG measurement.

Exclusion criteria

Unwillingness to cooperate. Implantation of pacemaker or cardioverter-defibrillator in the last 48 hours (to eliminate the possibility of infection introduction into the wound).

Methodology

For the possibility of data acquisition, a bespoke smartphone app was used (used both for iOS and Android) called MyKardi (Kardi-AI technologies Ltd., Olomouc, Czech Rep.) with the possibility of automatic connection of the belt with the smartphone, uninterrupted data recording, the possibility of annotating of symptoms in the ECG at a specific time and with automatic upload of anonymous data to the cloud once the measurement is finished. This data was used for viewing the 1-lead ECG

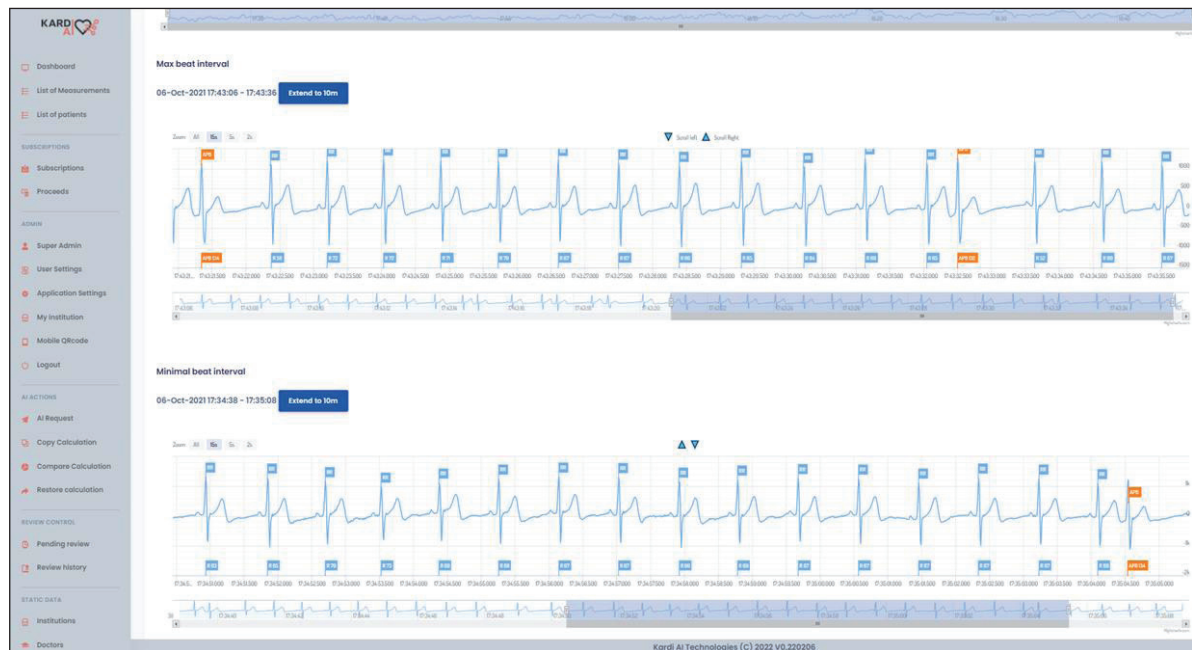


Fig. 1 – Web interface for evaluation of the recorded rhythm.

by physicians for subsequent evaluation and annotation. This was done in a bespoke web-based interface (Kardi-AI technologies Ltd., Olomouc, Czech Rep.) (Fig. 1).

Each individual heartbeat was evaluated by a physician and identified as one of five options: sinus rhythm (SR), atrial fibrillation (AF), supraventricular extrasystole (APB), ventricular extrasystole (VPB), noise (NOISE). Each evaluating physician had the option to change the annotation for each QRS complex at will (Figs. 2–5).

QRS complexes that met at least one of the following criteria were evaluated as NOISE: the type of rhythm could not be recognized at all; the physician was not 100% sure about

the type of rhythm; the rhythm could be recognized, but the evaluation was unpleasant for the physician because of the artefacts; the noise level exceeded over 50 % of the amplitude of the QRS complex in a given RRI. The duration of NOISE was not evaluated as the number of RRIs, but as the time between two RRIs evaluated as SR or AF.

Each ECG was evaluated twice by an experienced cardiologist to minimize the possibility of oversight and wrong ECG annotation, and then a third evaluation of each heartbeat was conducted for all ECG records by another physician with more than 18 years of experience in electrophysiology.



Fig. 2 – Sinus rhythm.

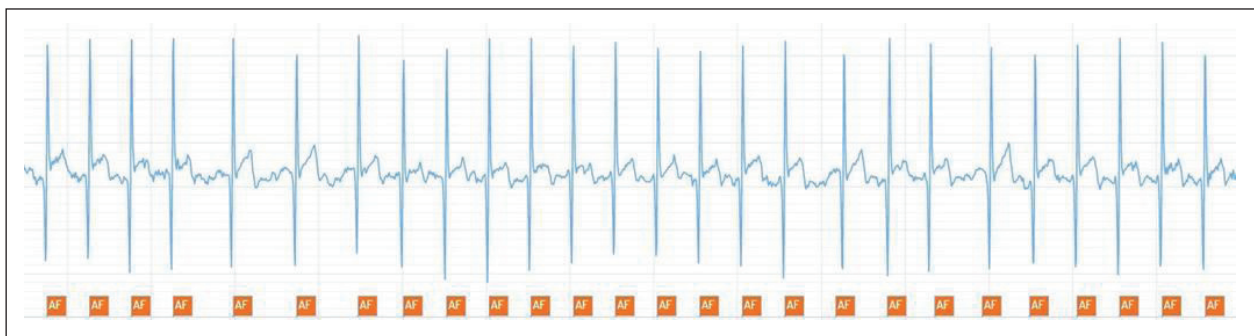


Fig. 3 – Atrial fibrillation.

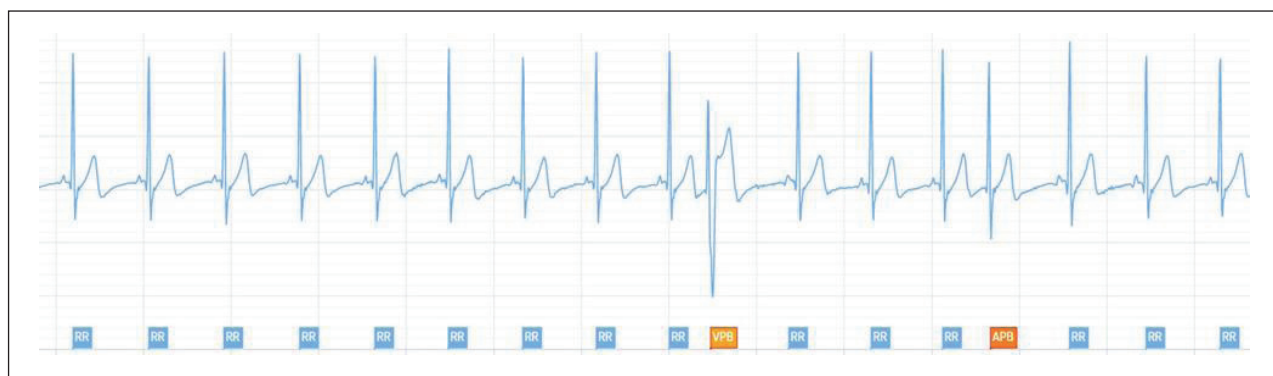


Fig. 4 – Atrial and ventricular premature beats.

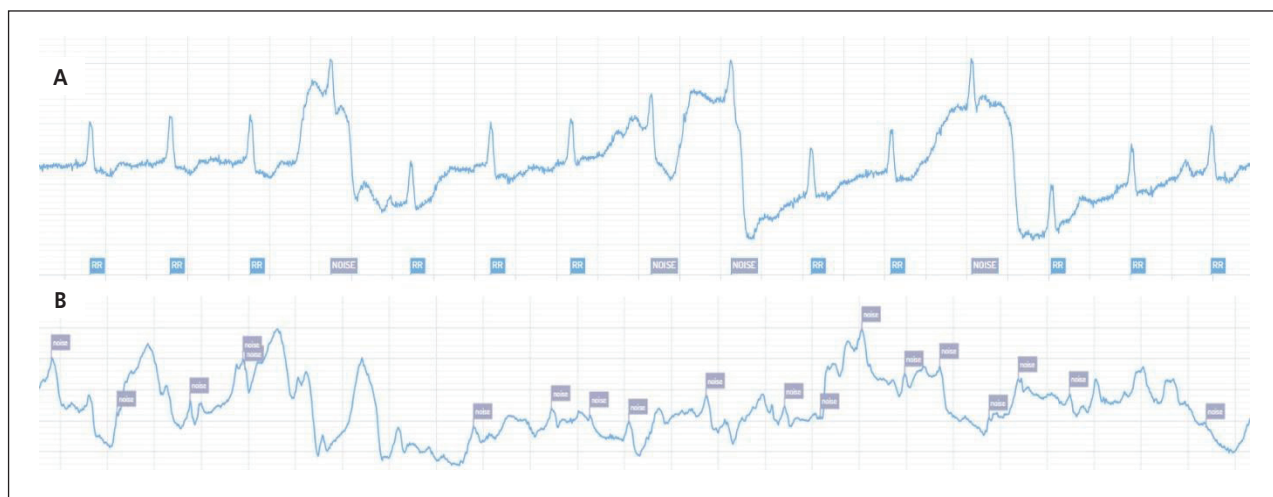


Fig. 5 – Noise. A: QRS complexes recognizable but ECG was still evaluated as not easy to interpret and thus annotated as noise. B: unrecognizable rhythm, ECG annotated as noise.

Group A (hospitalized patients): A 12-lead ECG was recorded to confirm the basic rhythm that was documented (SR or AF). Immediately afterwards, the patient was placed on a chest-belt as recommended by its manufacturer (the belt length was fitted to the patient's chest circumference and a moistened electrode elastic strap was applied below the patient's chest muscle) (Fig. 6).

An application on the smartphone was launched. Telemetry monitoring was left running at the same time as the data acquisition using the chest-belt, without interruption. Live-telemetry data was then evaluated for 10 minutes at the same time as the live-ECG on the smartphone application (Fig. 7).

The rhythm on the telemetry and the rhythm on the live-ECG from the smartphone screen were documented. If the physician was not sure, he documented the rhythm as UNCLEAR. Agreement on the type of rhythm on the telemetry and on the ECG from the chest-belt was evaluated and documented, both for the basic rhythm (SR vs AF) and for any premature contractions (APB vs VPB). The patient's movement was not limited in any way, including the possibility of being taken away for any examinations and/or procedures.

In the web application, the physicians marked all heartbeats, each separately, see above. The possibility of evaluating the basic rhythm and possible arrhythmias was re-



Fig. 6 – Polar H10 chest-belt.

corded, and in case of uncertainty, the overall record was concluded as UNCLEAR. In particular, the first minute of the ECG from the chest belt was evaluated in the web application, after any noise had subsided due to the belt being put on and its location corrected. The basic rhythm was evaluated as SR, AF or atrial flutter (AFLU). In case of any uncertainty about the underlying rhythm, the overall record was

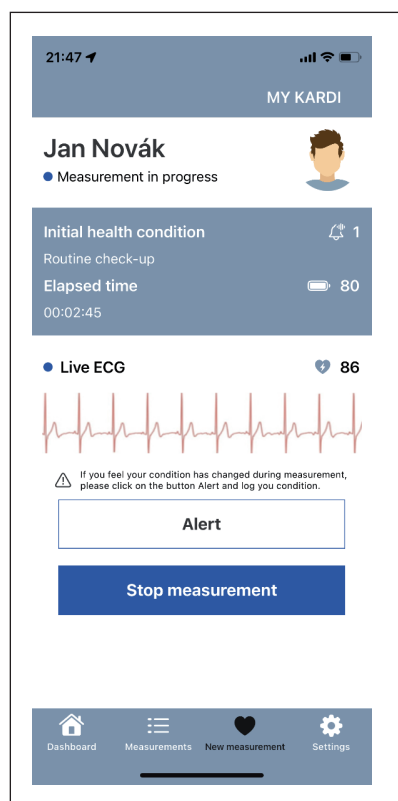


Fig. 7 – Bespoke application for recording ECG by means of Polar H10 chest-belt, Android/iOS, screenshot from smartphone application.

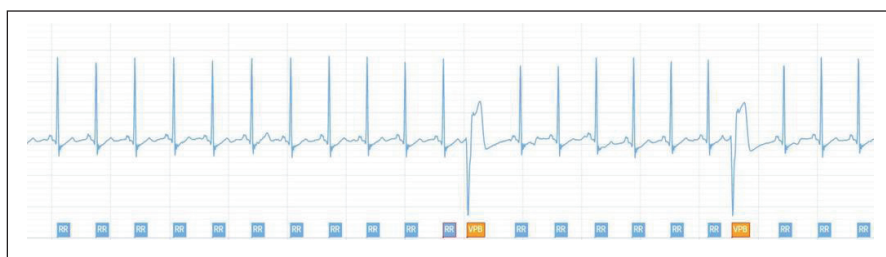


Fig. 8 – Premature ventricular contractions.

of 24 hours, during which a minimum of three measurements were required: 1. short test; 2. longer (> 1 hour) test; 3. evaluated measurements lasting 1–2 hours. The chest-belt was recommended to be fitted in accordance with the manufacturer's recommendations. Any problems could have been recorded in the smartphone app. In the web app, all heart beats were marked by the physicians, each heart beat separately, see above. The possibility of evaluating the underlying rhythm and possible arrhythmias was documented, and in case of any uncertainty the overall record was concluded as UNCLEAR.

In all patients the following data were recorded: Age, gender, weight, height, body mass index (BMI), rhythm (SR or AF), QRS (normal, bundle branch block, stimulated), presence of a device (pacemaker or defibrillator) and medical history. In healthy controls only gender was documented.

Results

A total of 161 patients was enrolled in the study so that there were identical numbers in each of the three groups (Group A, n=54; Group B, n=53; Group C, n=54).

Baseline characteristics of the population are shown in Table 1.

In group C, there were 30 (55.6 %) men.

Using a chest-belt, a total of 225 hours and 38 minutes of ECG was recorded (A: 71.5 hours; B: 82.4 hours; C: 71.7 hours), corresponding to 1 153 229 heartbeats (A: 444 500; B: 394 255; C: 314 474). For the values of average HR, percentage of noise, APBs, VPBs and AF, a following approach was used to obtain the final value: an average was counted for every single measurement and then an average was counted from these values per every category. The average heart rate was 76.6/min (A: 80/min; B: 76/min; C: 74/min). The presence of APBs was 5 317 (0.46 %) of all measured beats (A: 3 363 [0.76%]; B: 1 059 [0.27%]; C: 895 [0.28%]). The presence of VPBs was 5 631 (0.49 %) of all measured beats (A: 3 636 [0.82%]; B: 1 676 [0.43%]; C: 319 [0.10%]). AF was found in 18 measurements in group A, in 3 in group B and in 1 in group C (in 22/161 measurements in total). The presence of AF beats was 156 797 (13.6%) out of all measured beats (A: 131 465 [29.58%]; B: 20 660 [5.24%]; C: 4 672 [1.49%]). The presence of noise was 2.16 % of the whole time of measurement (A: 2.31%; B: 1.95%; C: 2.20%). This means that 1 128 319 heartbeats out of 1 153 229 were evaluated as easy to interpret.

In most cases, it was possible to reliably distinguish APB from ventricular extrasystole (VPB) (Fig. 8), as well as runs

concluded as UNCLEAR. This was then compared with the rhythm on the baseline 12-lead ECG. This first minute ECG evaluation was done separately from the whole ECG measurement evaluation by a different physician.

Group B (outpatients): A 12-lead ECG was recorded to confirm the basic rhythm and it was documented as SR or AF. Immediately afterwards, a chest-belt was put on the patient by the physician as recommended by the chest-belt's manufacturer and the application on the smartphone was started. A clinical visit of the patient was performed. Afterwards, the patient could have left the ambulance, his further movement or activity had not been limited in any way. After 1–2 hours of recording, the measurement was stopped and the patient went home.

In the web application, all heartbeats were marked by the physicians, each separately, see above. The possibility of evaluating the basic rhythm and possible arrhythmias was recorded, in case of any uncertainty the overall record was then closed as UNCLEAR. In particular, the first minute of ECG recording from the chest-belt was evaluated in the web application, after any noise had subsided due to the belt being put on and its location corrected. The basic rhythm was evaluated as SR, AF or AFLU. In case of any uncertainty about the underlying rhythm, the overall record was concluded as UNCLEAR. This was then compared with the rhythm on the input 12-lead ECG. This first minute ECG evaluation was done separately from the whole ECG measurement evaluation by a different physician.

Group C (healthy controls): Healthy controls were provided with the chest-belt for home use for a minimum

Table 1 – Baseline characteristics of the population

	Hospitalized (A), n = 54	Outpatient (B), n = 53
Male gender	31 (57.4%)	41 (75.9%)
Height (cm)	176.9±8.5	178.6±7.2
Weight (kg)	86.4±14.1	86.8±14.2
BMI	27.5±3.5	27.2±3.7
QRS <120 ms	33 (61.1%)	54 (100%)
LBBB	11 (20.4%)	5 (9.3%)
RBBB	4 (7.4%)	2 (3.7%)
Stimulated QRS	6 (11.1%)	0 (0.0%)
Pacemaker	6 (11.1%)	0 (0.0%)
Defibrillator	1 (1.9%)	1 (1.9%)
Ischemic heart disease	19 (35.2%)	5 (9.3%)
Arterial hypertension	41 (75.9%)	16 (29.6%)
Diabetes mellitus	22 (40.7%)	7 (13.0%)
Heart failure	20 (37.0%)	4 (7.4%)
Acute myocardial infarction	7 (13.0%)	0 (0.0%)
Infective endocarditis	3 (5.6%)	0 (0.0%)
Acute arrhythmia	14 (25.9%)	0 (0.0%)

Acute arrhythmia = hospitalization for acute arrhythmia.

BMI – body mass index.

In all patients with stimulated rhythm, this could be distinguished from spontaneous rhythm (Fig. 13).

In all cases, paroxysms of AF were clearly distinguishable based on a sudden change in HR from the HR-time graph (Fig. 14).

Group A

1. Possibility of evaluating the basic rhythm from a classical, 12-lead ECG: in 54/54 (100%) the rhythm was reliably determined by the physician.
2. Possibility of evaluating the basic rhythm from a 1-lead ECG obtained by means of a chest-belt, evaluation of the entire ECG (whole long recording) in a web application: in 51/54 (94.4%) the basic rhythm was reliably determined by the physician; 3 cases were evaluated as unclear. In all of these cases, all QRS complexes were stimulated by a pacemaker and the evaluating physician was not sure about the underlying rhythm since P waves were not easily to be distinguished from noise. On the 12-lead ECG, 2 of these 3 cases had AF, 1 SR.
3. Possibility of evaluating the basic rhythm from a 1-lead ECG obtained by means of a chest belt, evaluation of the first minute of the ECG after any noise has subsided due to the belt being put on and correction of its location; evaluation of the ECG from a web application. In 51/54 (94.4%) the basic rhythm was determined by the physician; 3 cases were eval-

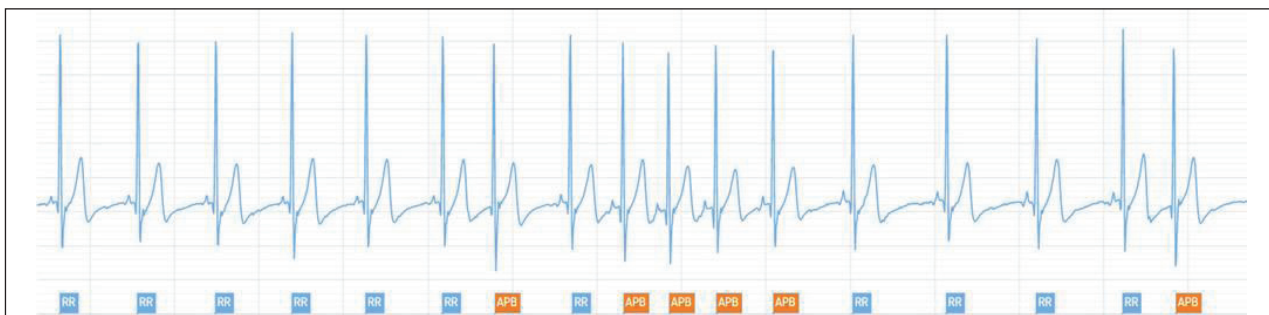


Fig. 9 – APBs, single and in clusters.

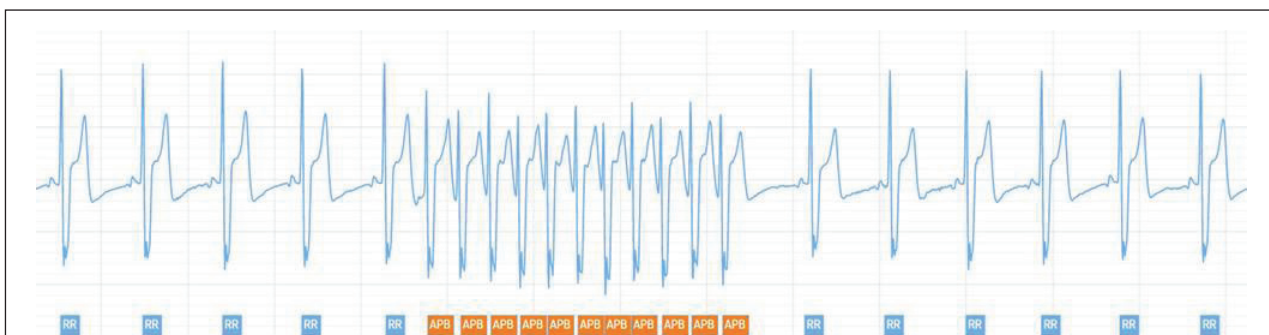


Fig. 10 – Atrial tachycardia.

of atrial and ventricular tachycardia (Figs. 9–11). The ambiguity in the APB vs VPB assessment occurred in the VPB of septal localization with respect to their rather narrow QRS. In all patients with bundle branch block, this could be reliably distinguished from normal ECG (Fig. 12).

uated as unclear. When comparing the evaluated rhythm with a 12-lead recording, the rhythm match was in 50/54 (92.6%). The absence of match in the determination of the heart rhythm was documented in 4 cases. In 3 cases evaluated as unclear, all QRS

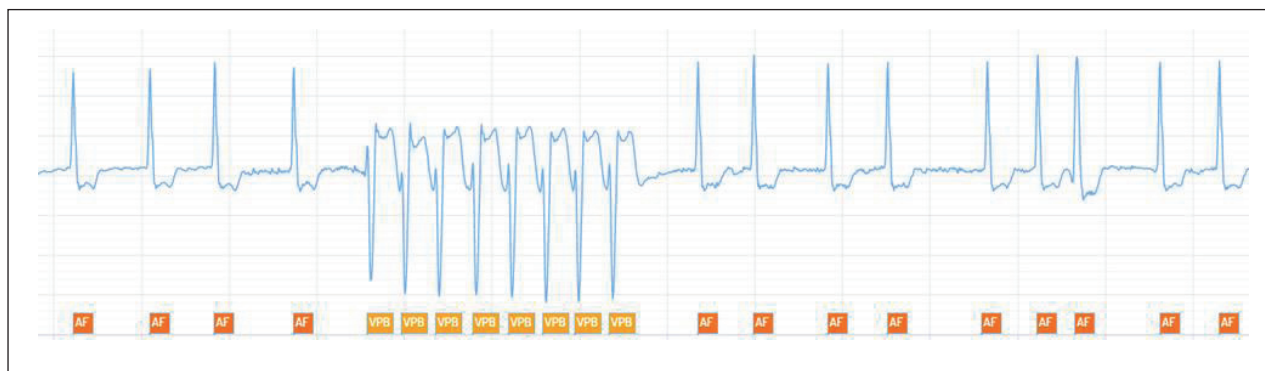


Fig. 11 – Non-sustained ventricular tachycardia.

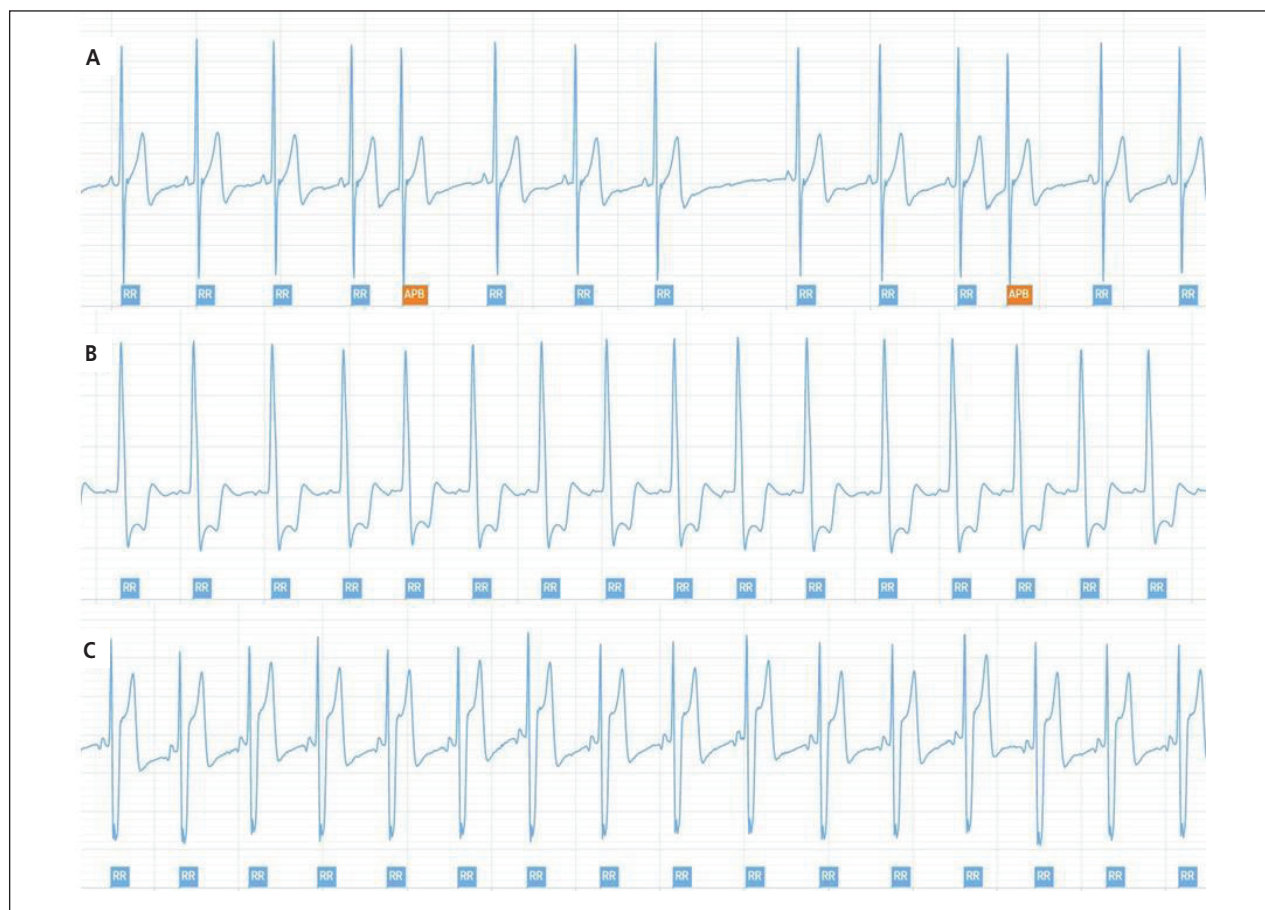


Fig. 12 – QRS width. A: narrow QRS; B: LBBB; C: RBBB.

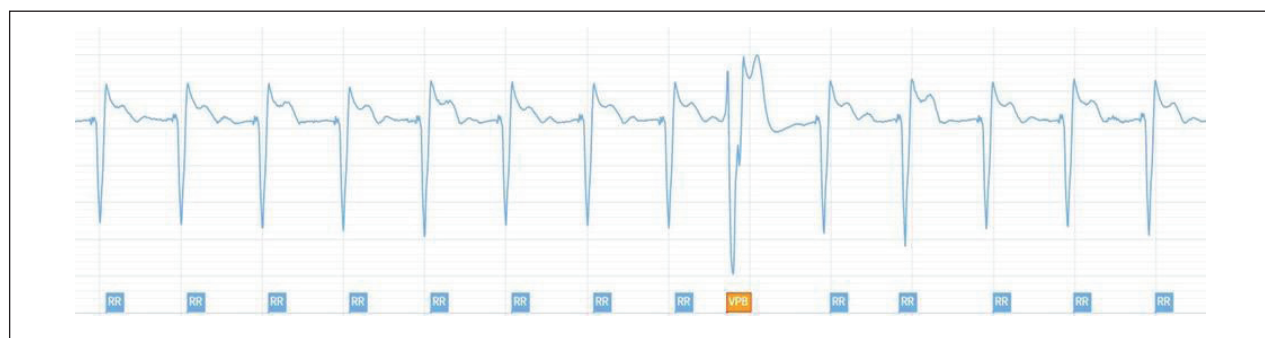


Fig. 13 – Stimulated rhythm.



Fig. 14 – Heart-rate time graph. Peaks in heart-rate correspond to four AF paroxysms during a single measurement.

complexes were stimulated by a pacemaker and the evaluating physician was not sure about the underlying rhythm since P waves were not easily to be distinguished from noise. 2 of these 3 cases had AF, 1 SR. In the remaining 1 case, live ECG was evaluated as SR with frequent APBs but 12-lead ECG revealed AF.

4. Possibility of evaluating the basic rhythm from a 1-lead ECG obtained by means of telemetric ECG monitoring in real time. In 51/54 (94.4%) cases, the rhythm was determined reliably by the physician. The determination ambiguity in 3 cases was in patients with AF and stimulated QRS complexes.
5. Possibility to evaluate the baseline rhythm from 1-lead ECG obtained by chest-belt in real time, evaluation of live-ECG from a smartphone screen during telemetry monitoring (10 minutes). In 50/54 (92.6%), the rhythm was determined reliably by the physician. The determination ambiguity in 4 cases was in patients with stimulated QRS complexes (2 cases had AF, 1 AFLU, 1 SR).
6. Comparison of evaluation of the baseline rhythm from 1-lead ECG obtained by chest-belt in real time, evaluation of live-ECG from smartphone screen and 1-lead ECG obtained by real-time telemetric ECG monitoring. The match was in 53/54 patients (98.1%), including 3 cases that were evaluated as unclear both from telemetry and from live-ECG in app. In 1 case, a correct diagnosis of AFLU was done from telemetry but live ECG from app was evaluated as unclear.

Group B

1. Possibility of evaluating the basic rhythm from a classical, 12-lead ECG: in 54/54 (100%) the rhythm was reliably determined by the physician.
2. Possibility of evaluating the basic rhythm from a 1-lead ECG obtained by means of a chest belt, evaluation of the entire ECG in a web application: in 54/54 (100%) the basic rhythm was reliably determined by the physician.¹
3. Possibility of evaluating the basic rhythm from a 1-lead ECG obtained by means of a chest belt, evaluation of the first minute of the ECG after any noise has subsided due to the belt being put on and correction of its location; evaluation of the ECG from a web application. When comparing the evaluated rhythm with a 12-lead recording, the rhythm match was in 54/54 (100%).

Group C

1. Possibility to evaluate the basic rhythm from a 1-lead ECG obtained by means of a chest-belt, evaluation of the whole ECG in a web application: in 54/54 (100%) the basic rhythm was reliably determined by the physician.

Discussion

The main finding of this study is that ECG interpretation from the Polar H10 chest belt is possible in non-selected cardiology patients under casual conditions during hospitalization, in the out-patient department as well as healthy controls at home, regardless of basic rhythm, QRS width, bundle branch block, presence of pacemaker or cardioverter-defibrillator, or an active stimulated rhythm, in real-life conditions, regardless of the physical activity performed. In our trial, out of 1 153 229 beats, 1 128 319 (97.84%) were evaluated as easily recognizable and categorizable by a cardiologist. Under real-life conditions, only 2.16% of all beats were evaluated as too noisy or generally as unpleasant to quickly determine the presence and type of QRS and type of the rhythm. The value of noise was highest in hospitalized patients and lowest in outpatients. The reason for this finding could be more artefacts due to larger amount of tremor in acutely ill, more frail patients and bumping on the belt during examinations and various procedures at hospital since the patients were not limited to undergo any standard procedure or examination. Lowest level of noise was anticipated in relatively sedentary outpatients during a clinical visit and a somewhat higher level of noise in healthy controls can be explained by them actively moving.

We have documented an excellent match of a decision about the heart rhythm from a single-lead chest-belt ECG recording with a standard 12-lead ECG. In outpatients, the match was in all cases. In hospitalized patients, there was a 94.4% of match of 12-lead ECG with the result of the chest-belt analysis and a 92.6% of agreement with a fast evaluation of the first minute of ECG from the chest-belt. The usefulness of a live real-time ECG from the chest-belt in an app on a smartphone screen to decide about the cardiac rhythm was comparable to a live telemetric ECG recording.

Currently, the standard of care of screening for arrhythmias is Holter ECG. However, current Holter ECG devices are bulky and cumbersome and their analysis takes a significant time. These devices are and will not be avail-

able for all patients for longer periods of time based on a limited supply, limitations in reimbursement, need for a putting on by a skilled nurse and a time needed for an analysis and especially three visits in an out-patient department needed by a patient (putting on, putting off – analysis – visit). Patients are not able to be monitored exactly at the time of their issues and this process must be often done several times. Moreover, patients are reluctant to wear generally any Holter ECG monitors for longer periods of time and several times a year and to visit their cardiologist several times to obtain a result. Some of these pitfalls are overcome using implantable loop recorders. These are, however, surgically implanted devices with a high cost, a need for a specialized technician to evaluate the recordings and a very limited number of devices per center per year that are allowed to be reimbursed by health insurance companies. Several portable ECG recorders became recently available. They are owned by the patient and thus can be used in time of need. However, their use is based on holding a device with hands for tens of seconds. They are suitable for short ECG recordings at home but useless for longer measurements. Their use is thus limited for validation of correlation of symptoms and arrhythmias. These limitations are shared with smartwatches with ECG acquisition possibility. A lot of devices like smartwatches and armbands use an optical PPG sensor for HR analysis. PPG signals are prone to noise and motion artifacts caused by body movement, muscular movement and sensor dislocation. Moreover, signal acquisition is also affected by skin color, ambient light, and body temperature. Thus, during movement and generally under any sub-optimal conditions, PPG sensors are unreliable.

A very interesting option to analyze heart rhythm is a chest-belt with an ECG sensor. These devices are designed to be comfortable, lightweight, compact and to function equally well under optimal and sub-optimal conditions, unlike PPG sensors. The original determination of the usage of HR monitors, such as chest-belts, was generally the assessment of RRs. With the correct determination of RR intervals, the chest-belt can then be used relatively easily for HRV evaluation. Several validation studies have verified the accuracy of the RRI evaluation by HR monitor compared to ECG Holter.^{16–19} However, most of the data in these studies were obtained under resting conditions (lying down, sitting, standing still). Significantly fewer studies are available that assessed the quality of RR signals under exertion. We have data mostly from cyclists and to a lesser extent from runners.^{20–22} In a number of studies, the Polar H7 chest-belt has been used as a reference device for wearable HR measurement devices in recent years.^{18,23,24}

The new generation Polar H10 chest-belt, which was used in this study, has a number of improvements for HR and HRV measurements, according to the manufacturer. It provides raw ECG and RR time intervals with a resolution of 1 ms. This device was also validated against a reference device (Holter ECG) for the quality of RRs measurements. With low-exertion activities such as reading, housework and walking, Polar H10 had excellent signal quality, comparable to Holter ECG (99.6% for H10 vs 94.6% for Holter ECG), with an RRI detection error of

0.15% (0.16% error rate for Holter ECG).¹³ This error was even lower than in earlier studies, when it was reported from 0.27 to 2.20%.^{17–18,21,25,26} During jogging and strength training, Polar H10 showed a 0.56% error rate in determining RRs, which was consistent with a 0.32–0.71% error rate when using Polar H7 belt for ergometry and Polar T61 belt for mountain running (20, 22). During intensive activities, the Holter ECG showed a significantly higher error rate (10.21% of RRs). The quality of the RRs assessment during high-intensity activities was thus significantly higher in the chest-belt (99.4% for H10 vs 89.8% for Holter ECG). Motion artefacts can thus lead to more artefacts in the Holter ECG than in the chest-belt, which is primarily designed for more pronounced activities. Polar H10 can thus be considered as the gold standard for the evaluation of RRs during intensive sports activities.¹³

In our work we evaluated 2.16% of RRs as noise, however, the criteria for the evaluation were set very softly with an easy interpretability of the rhythm in mind, when in the vast majority of RRs annotated as noise it was possible to detect the R interval. However, if the noise amplitude exceeded 50% of the amplitude of the R peak, or the physician evaluated the RRI as unpleasant to quickly determine the type of QRS/rhythm, it was evaluated as noise. The reason for this decision was that we did not want to detect the percentage of detectable QRS complexes, but a percentage of QRS complexes, whose evaluation would be considered annoying by a cardiologist in normal practice, which could lead to a decrease in willingness to evaluate ECGs from the chest-belt. In addition, transient intervals with a greater number of artefacts after putting on and before removing the belt were included in the noise. The real number of RRI errors in cardiology patients in common practice will therefore certainly be significantly lower. The percentage of noise may also be higher because all heartbeats were evaluated, in contrast to the otherwise used approach of the manual evaluation of RRs in case there is a change in RRI by more than 20%.²⁷ In some patients with stimulated ventricles, RRs were easily recognizable but the P waves were harder to discern. These measurements were evaluated as unclear despite a low level of noise per se since they would pose an unacceptable workload on the evaluating physician. In patients with pacemakers and implantable defibrillators and a high percentage of stimulated rhythm the chest-belt ECG measurement might be unreliable.

Polar H10 with the Pro strap is specially designed to protect against electrical noise and enable proper ECG measurements to be made. There is little clinical data to evaluate heart rhythm disturbances using a chest-belt. A 1-lead ECG may appear inferior to multiple-lead ECG records. However, in an analysis of the interpretation of a 1-lead ECG in 1,000 outpatients >75 years of age by four physicians, sensitivity 94.4% and specificity 94.6% were achieved compared to a 12-lead ECG.²⁸ Similarly, in another study of 100 patients in a cardiology clinic, sensitivity and specificity were 92% and 96%, respectively.²⁹ Lown et al. evaluated the possibility of using several devices (AliveCor, WatchBP, BG2, Polar H7 chest-belt) in patients in a general practitioner's office and concluded that 1-lead ECG from the chest-belt can be used to detect AF with sensitivity and specificity above 95%. As in our case,

they warn about the possibility of incorrect detection in patients with AFLU.¹⁴ They have excluded patients with a pacemaker. Otherwise, the use of the Polar H7 chest-belt was seamless, well received by patients for comfort, and multiple attempts were not necessary to achieve a diagnostic ECG. By contrast, 42/418 (10%) ECGs recorded using AliveCor were assessed by the algorithm as non-classifiable. Such a proportion of automatically non-assessable ECG recordings would lead to the need for a personal classification by a physician with a significant burden on the evaluating cardiologist.

In our study, the recording was evaluated as unclear in 3/162 (1.85%) cases. All of these cases were hospitalized patients with stimulated QRS complexes by a pacemaker. Otherwise, the basic rhythm was reliably classified by the physician, both in hospitalized and outpatients when the chest-belt was put on by a physician and healthy controls who performed the ECG measurements themselves at home.

Hartikainen et al. used Suunto chest belt in 220 patients for detection of AF. Contrary to our work, patients were selected, measured briefly and under optimal conditions – the measurement took 5 minutes, the patients were at rest lying down and excluded were patients with BMI >33, pacemakers and defibrillators and patients with a bundle branch block.¹⁵ The standard against which the ECG from the chest-belt was compared was the ECG assessment from the 3-lead Holter ECG, done by a cardiologist. As in our case, the ECG assessment from the chest-belt was performed with the help of a homemade application on a smartphone. The main finding of the study was that the quality of the ECG from the chest-belt was sufficient for the evaluation of AF by both the cardiologist and automatically using the previously described algorithms.^{30,31}

The chest-belt is thus sufficiently validated for the correct detection of RRs under all conditions, at rest and with varying levels of physical activity. Acquisition of an ECG by the patient is easy with the right software. As we have shown, in a wide range of CVD patients, hospitalized and outpatients alike as in healthy controls, it is possible to classify rhythm without difficulty, interpret each individual heartbeat at a small % of RRs that are either non-evaluable or more difficult to evaluate. The interpretation of an ECG from the chest-belt is comparable to a 12-lead ECG as well as to a telemetric ECG recording that has the same level of ECG quality and can be interpreted with a similar certainty. One must be aware though of the likelihood of a possible misinterpretation of rhythm in patients with stimulated QRS complexes and AFLU with regular RRs and a fast HR. In both cases, the underlying rhythm can be difficult to distinguish from SR with a higher rate of artefacts. This issue however arises mostly when one evaluates a short ECG recording. With a long ECG measurement, the underlying rhythm can be assessed with a great certainty, especially when periods of minimal or no noise are available. The interpretation in patients with devices can be facilitated by interrogation of the device. One must be aware of this potential issue though. The last potential problem in rhythm interpretation that we encountered in this study was the evaluation of VPBs of septal localization, which were difficult to distinguish from APBs from the 1-lead ECG due

to the narrow QRS complex. In these cases, if there are doubts about differentiation of APBs and VPBs, a Holter ECG measurement and/or repeated 12-lead ECGs should be scheduled for a final clarification. A thorough study comparing 1-lead ECG from the chest-belt and 12-lead ECG in real time in patients with APBs and VPBs from all possible locations might clarify this issue and further limit the need for a Holter ECG verification.

Despite the low percentage of either more difficult to interpret or uninterpretable QRS complexes, these can lead to false positive findings that would pose a significant burden to a cardiologist. It is therefore necessary to create algorithms or use the possibilities of artificial intelligence (AI) to eliminate noise. Once the noise is removed and we have correctly detected RRs, the diagnosis of AF can be reasonably reliably determined even by existing algorithms with an accuracy of >95% from a 1-lead chest-band ECG.^{30,31}

The classification of all heart beats evaluated and verified by several physicians can serve not only as a demonstration of the possibility of interpretation of ECG from the chest belt in non-selected patients with various CVDs, but also as a basis of evaluation of AI / advanced algorithms for clinical validation of noise elimination and automatic determination of individual rhythm types. In the future, the chest-belt can potentially serve as a screening tool for the detection of arrhythmias such as AF, measurement of % of APBs and VPBs, the detection of longer pauses between each QRS complex, monitoring of AF burden, HR during AF and presence of runs of non-sustained ventricular tachycardia. Considering the possibility of ownership of a chest-belt by the patient, it can be available anytime and anywhere, especially in times of symptoms. Mainly it can serve as a long-term screening monitoring tool to detect asymptomatic episodes of AF and potentially reduce the cost of opportunistic screening for arrhythmias. Using a chest-belt, we have found an asymptomatic AF paroxysm in 1/54 healthy controls. It has been confirmed on an additional Holter ECG and the patient was put on medication. However, this was found manually and to validate automatic detection of arrhythmias from long chest-belt recordings further prospective studies are needed.

Study limitations

The main limitation of the study was the absence of a Holter ECG in all patients throughout the chest-belt ECG recording. However, a comparison of the quality and accuracy of the QRS signals of the thoracic belt vs. the Holter ECG has already been performed,¹³ as well as a comparison of the quality of the ECG signal and the accuracy of the detection of the AF thoracic belt vs. the Holter ECG.^{14,15} We have used a different approach, not to state a diagnosis from the chest-belt recording and to compare it with a diagnosis from a Holter ECG but rather examine each and every heart beat in all recordings manually. Each heart beat was evaluated at least three times by several experienced cardiologists and only then finally annotated. All individual heart beats from the chest-belt ECG were evaluated as certain (annotated as SR, AF, APB,

VPB) or as uncertain in case of noise or any doubt or in case of just generally poor-quality signal. Moreover, the accuracy of this evaluation was manually checked against a 12-lead ECG and a 10-minute telemetry recording with an almost perfect match in all cases but patients with a stimulated QRS complexes.

Another limitation of the study is the absence of evaluation of automatic noise elimination algorithms and algorithms or artificial intelligence, automatically evaluating the heart rhythm. The data obtained in this evaluation, manual annotation of each heartbeat, can nevertheless be used as the gold standard for assessing the accuracy of these techniques.

Conclusion

The ECG obtained from the chest-belt in hospitalized patients and outpatients with a wide range of cardiovascular diseases, as in healthy individuals, is usable in real practice for evaluation of baseline rhythm, atrial fibrillation and premature contractions with a minimal proportion of difficult to interpret recordings due to artefacts. Caution should be exercised in interpretation of the ECG in patients with stimulated rhythm, in patients with atrial flutter and in evaluating premature ventricular beats of septal origin since they can look very similar to premature atrial beats. The chest belt seems ideal to be used as a means for continuous monitoring of ECG, evaluation of rhythm and screening of atrial fibrillation with minimal proportion of noise regardless of patient activity if used well.

Acknowledgements

We would like to thank to David Skála for creation of the web-based interface for ECG evaluation, Pavel Digana for creation of the mobile application that enabled ECG acquisition by the means of a chest-belt and Stephen Burke for a great help with organization and especially lending of the chest-belts.

Conflict of interest

TS is one of the co-founders of Kardi-AI Ltd., a company that has provided a complex software environment for the recording, storing and analysis of ECG using the Polar H10 chest-belt. For maximum clarity, all data used in this study were checked by five independent cardiologists (MR, JV, MV, JF, MT) and are stored in full length and available upon reasonable request.

Funding

Supported by SUG FNOL 87-28: Verifikace dlouhodobé efektivity katetrizační ablace paroxysmální fibrilace síní v udržení sinusového rytmu za použití moderních telemedicinských technologií.

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