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Original Article

Validity of the software-hardware complex “Rytm” for measuring the RR intervals and heart rate variability at rest

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Abstract:
In order to perform the correct analysis of heart rate variability (HRV) by newly designed devices, it is necessary to confirm the sufficient level of accuracy in the registration of RR intervals. We have examined the accuracy of RR time series measurements by software-hardware complex “Rytm” (SHC “Rytm”) and validity of subsequently calculated HRV indexes at rest.The subjects were 20 healthy male adults20.0±0.27 years old. Recording of RR intervals was performed simultaneously with ECG recorder (CardioLab CE12), Polar RS800, and SHC “Rytm” during 5 minutes in the supine position at rest. HRV indexes were calculated by Kubios HRV 2.1. Intraclass correlation coefficients (ICC = 0,951–0,954), Bland–Altman limits of agreement (LoA = -22,89–22,54 ms for SHC “Rytm” vs Polar) and paired t-test showed good agreement between all the devices in the measurements of RR intervals. No difference ($P > 0.05$) for HRV indexes, calculated from Polar RS800 and SHC “Rytm” data was found. There are some differences in HRV indexes, derived from the RR data of CardioLab CE12 and SHC “Rytm” (LF,% and pNN50) and also CardioLab CE12 and Polar RS800 (STD RR, RMSSD, pNN50, SD1, SD2). The results suggest that the SHC “Rytm” is able to capture series of RR intervals as reliable as those obtained by ECG and Polar RS800.We found good agreement between most of the HRV indexes based on data of SHC “Rytm” and medical electrocardiographic system.
KeyWords: electrocardiography, Polar RS800, Bland–Altman diagram, intra class correlation coefficient

Introduction

The important task for modern physiology is remote monitoring of the functions of physiological systems of the human organism during the competitive and training activity, in the case of emergency and in medical institutions. It is necessary to assess the loads intensity, to track the time course of training adaptation or illness progression and to avoid pathological changes. For this purpose, the instruments of remote (telemetry) control of the physiological functions have been widely developed (Dunn et al., 2018; Taj-Eldin et al., 2018). Such instruments are mainly represented by health monitoring software-hardware complexes based on the wearable sensors monitoring body motion, breath, skin temperature, metabolism parameters, heart rate and other parameters of cardiovascular system (Dias & Cunha, 2018; Liu et al., 2018; Majumder et al., 2017). The parameters of the cardiovascular system are used as indicators of the intensity and adequacy of physical loads, the level of autonomic regulatory systems functioning, as the predictors of pathological changes.

It is well known that analysis of heart rate variability (HRV) is one of the effective methods to evaluate the physiological changes which occur in the response to physical loads (Bellenger et al., 2016; Dong, 2016). Some recent researches claimed that HRV may serve as useful parameters for monitoring the physical fatigue development, level of chronic cardiovascular autonomic adaptations, controlling the exercise intensity, provide information for personalization of sports training and for the early diagnosis of pathological changes (Bellenger et al., 2016; Dong, 2016; Silva et al., 2014).

The software-hardware complex “Rytm” (SHC “Rytm”) is elaborated for the automatic analysis of HRV and basic indexes of human hemodynamic. The “Rytm” software is written in Embarcadero Delphi XE8, operates on the MS Windows 10 platform with hardware supporting the technology of wireless data transmission by protocol Bluetooth 4.0 or higher. The wearable heart rate sensor is used to record the duration of the RR intervals. In order to perform the correct analysis of HRV by newly elaborated device, it is necessary to confirm the accuracy in the registration of the RR intervals. The significant errors in the registration can lead to incorrect

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calculation of HRV indexes and mistakes in assessment of the physiological changes. Usually the accuracy of the registration is estimated by comparison of the data, obtained from two devices, one of which is considered to be a reference (“golden standard”).

In particular, such studies have been performed for the Garmin 920 XT (Cassirame et al., 2017), PolarS810 (Braga et al., 2016; Gamelin et al., 2006, 2008; Kingsley et al., 2005; Barbosa et al., 2014; Nunanet al., 2008; Porto &Jr, 2009; Vanderlei et al., 2008; Weippert et al., 2010), Polar RS800 in various modifications (Hernando et al., 2018; Barbosa et al., 2014; Montaño et al., 2016; Wallén et al., 2011), Polar V800 (Caminal et al., 2018; Giles et al., 2015; Giles & Draper, 2018), Equivital EQ02 (Akintola et al., 2016) and Suunto t6 (Weippert et al., 2010) monitors. As the reference devices the medical ECG recorders (Cassirame et al., 2017; Giles & Draper, 2018; Hernando et al., 2018; Barbosa et al., 2014 and others) or holter ambulatory ECG recorders (Akintola et al., 2016; Braga et al., 2016; Caminal t al., 2018) were used. Comparisons were performed on the basis of the data obtained in rest (Cassirame et al., 2017; Gamelin et al., 2008; Giles & Draper, 2018; Nunan et al., 2008; Wallén et al., 2011; Weippert et al., 2010), in the case of changing the position of the body (Cassirame et al., 2017; Gamelin et al., 2006, Giles et al., 2015; Barbosa et al., 2014; Montaño et al., 2016; Porto et al., 2009), during exercise performance in the laboratory (Braga et al., 2016; Cassirame et al., 2017; Giles & Draper, 2018; Hernando et al., 2018; Kingsley et al., 2005; Vanderlei et al., 2008; Weippert et al., 2010) or in mountain conditions(Caminal et al., 2018). In most of the studies, researchers compared both RR intervals and HRV indexes, calculated on the basis of RR intervals time series (Akintola, 2016; Caminal et al., 2018; Gamelin et al., 2008; Giles & Draper, 2018; Giles et al., 2015; Hernando et al., 2018; Kingsley et al., 2005; Nunan et al., 2008; Weippert et al., 2010).

At the same time, only the HRV indexes were compared in some publications (Braga et al., 2016; Cassirame et al., 2017; Barbosa et al., 2014; Wallén et al., 2011). The presence of a large number of publications testifies the necessity of the investigation of the accuracy of raw data and derived HRV indexes, obtained by different registration systems.

The main purpose of the present study was to examine the accuracy of RR time series measurements by SHC “Rytm” and validity of subsequently calculated HRV indexes in a state of physiological rest.

Material & methods

Participants were twenty healthy male adults (aged 20.0±0.27 years, height 181.2 ± 1.8 cm, weight 74.2 ± 1.9 kg), non-smokers, and none was taking any medication. All subjects provided informed consent to participate in the study. The procedures were accorded to the ethical standards of the relevant national, institutional or other body responsible for human research and experimentation, and to the principles of the World Medical Association's Declaration of Helsinki.This study was approved by the Ethical Committee of Lviv State University of Physical Culture named after Ivan Boberskyj

Measures. For comparative analysis, the registration of RR intervals was performed simultaneously by ECG recorder (CardioLab CE12, XAI-Medica, Kharkiv, Ukraine), Polar RS800 (Polar Electro Oÿ, Kempele, Finland) and SHC “Rytm” (LSUPhC, Lviv, Ukraine). We used the Polar RS800 as the second “golden standard” device due to a large number of previous studies that confirmed the high level of accuracy of this device (Hernando et al., 2018; Barbosa et al., 2014; Montaño et al., 2016; Wallén et al., 2011), as well as the promising use of the Polar RS800 for the analysis of the accuracy of recording of RR intervals during exercise performance. The Polar H7 (Polar Electro Oÿ, Kempele, Finland) served as a heart rate sensor at SHC “Rytm”, data was transmitted by Bluetooth and registered with the “Rytm” software.

Procedures. The electrode belts of Polar RS800 and SHC “Rytm” sensor were placed just below the chest muscles as described by the manufacturer. The electrodes of the ECG were placed according to second standard lead. Experiments were performed in accordance with the requirements of the European Society of Cardiology and The North American Society of Pacing and Electrophysiology (Heart rate variability: standards of measurement, 1996). All subject rested comfortably during the recording in a supine position in the absence of external stimuli, the rhythm of breathing was not controlled. Registration time was 5 minutes.

Analysis. In order to examine the accuracy of measurements, the RR records obtained by SHC “Rytm”, CardioLab CE12 and Polar RS800 were imported into MS Excel version 2010 (Microsoft Inc., USA), RR intervals time series were synchronized and analyzed. Standard statistical methods were used to calculate the means and standard deviations. A paired t-test or, when appropriate, a paired Wilcoxon test, was used to detect the presence of systematic difference. The Bland–Altman statistical approach, calculation of intraclass correlation coefficient (ICC) and limits of agreement (LoA) were used for comparison. Statistical significance was set at $P = 0.05$ level for all analysis. Statistical analysis was carried out using MS Excel 2010 and OriginPro 9.1.

Results

The number of detected RR intervals was 4607 for each of the devices. The mean value of the RR interval, determined according to the data of different devices, ranged from 988.8 to 989.5 ms with a standard error of the mean 1.97 – 1.99 ms (Table 1).

Table 1. Statistical description of the sets of RR intervals recorded by different devices

Index	CardioLab CE12	Polar RS800	HSC "Rytm"
Number of intervals	4607	4607	4607
Mean (ms)	988,77	989,53	988,95
SEM (ms)	1,99	1,97	1,99
SD (ms)	134,79	133,66	134,86

Note: SEM – standard error of the mean, SD – standard deviation

The most common approaches to analysing the repeatability of data obtained by different devices are plotting of Bland–Altman diagram, determination of the limits of agreement (LoA) and the calculation of intraclass correlation coefficient (ICC) (Doğan, 2018; Watson & Petrie, 2010; Giavarina, 2015). Bland–Altman plot for CardioLab CE12 and SHC "Rytm" is presented in Fig. 1., suggested very good agreement among the devices.

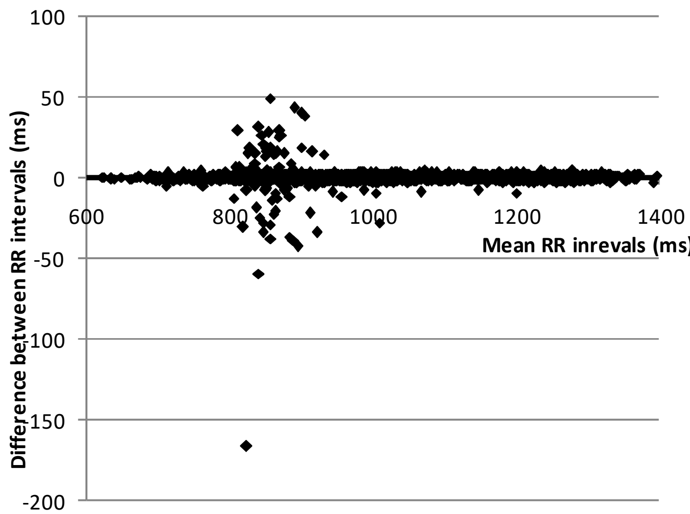

Fig. 1. Bland–Altman plot of RR intervals comparison between CardioLab CE12 and SHC "Rytm" (n = 4607) for all subjects. Limits of agreement are indicated by horizontal lines.

We found that average difference in RR intervals was -0.177 ms and the LoA were from -22.89 ms to 22.54 ms when comparing CardioLab CE12 and SHC "Rytm" (Table 2). The LoA was found to be larger for other pairs of the devices.

Table 2.Analysis of the repeatability in RR time series measured by different devices (n = 4607)

Index	Pairs of compared devices		
	CardioLab CE12 – Polar RS800	CardioLab CE12 – HSC "Rytm"	Polar RS800 – HSC "Rytm"
Mean ΔRR (ms)	-0.756	-0.177	-0.579
SEM ΔRR (ms)	40.59	11.59	42.22
Limits of agreement (ms)	-80.32 – 78.81	-22.89 – 22.54	-83.33 – 82.17
Intraclass correlation coefficient	0.954	0.996	0.951
P value	0.21	0.30	0.34

Note: ΔRR is the difference in the duration of the RR interval recorded by two different devices.

The intraclass correlation coefficients (ICC) were determined based on the Weir model 3.1 (Koo & Li, 2016; Watson & Petrie, 2010; Weir, 2005). The value of ICC was 0.996 between CardioLab CE12 and SHC "Rytm" (Table 2), indicated a very high repeatability of the data (Koo & Li, 2016). High ICC levels (0.951-0.954) were also found for the data of other devices. The RR intervals were normally distributed according to the Kolmogorov-Smirnov test. Therefore we had used the Student paired t test, which did not display any significant differences ($P > 0.05$) between the time series of RR intervals recorded by different devices (Table 2).

On the next stage of the research we tested the hypothesis of the repeatability of RR time series for each of the participants. It is necessary, because individual differences may influence the results of the HRV indexes calculation. The Wilcoxon matched pairs test was used to compare individual RR time series, as their distribution deviate from normal according to the Kolmogorov-Smirnov test. The obtained results indicated absence of statistically significant difference between sets of individual RR intervals data, obtained by the devices (Table 3). To verify the identity of the RR time series, we also applied correlation analysis, which showed very close correlation (r = 0.91–0.97) between the data sets, recorded by different devices (Table 3).

Table 3.Comparison of individual RR time series obtained by various devices (n = 20, M ± SEM)

Index	Pairs of compared devices		
	CardioLab CE12 – Polar RS800	CardioLab CE12 – HSC “Rytm”	Polar RS800 – HSC “Rytm”
P value	0.56 ± 0.05	0.67 ± 0.06	0.69 ± 0.05
r value	0.93 ± 0.06	0.97 ± 0.02	0.91 ± 0.06

The final goal of the registration of RR time series is calculation of individual HRV indexes. That is why we intended to test if the obtained LoA for RR data were narrow enough to avoid substantial differences in the derived HRV indexes (Myles & Cui, 2007). For this purpose, a comparison of HRV indexes, derived by “golden standard” software from RR time series recorded by different devices, was conducted. The HRV indexes were calculated using Kubios HRV 2.1 (Kuopio, Finland) and results are presented in Table 4. The differences between groups were determined by paired t-test or paired Wilcoxon test, depending on Shapiro–Wilk criterion.

Table 4.Comparison of heart rate variability indexes (M ± SEM), derived from the RR data from different devices

HRV index	Recording device			CardioLab CE12 – Polar RS800		CardioLab CE12 – HSC “Rytm”		Polar RS800 – HSC “Rytm”	
	Cardio Lab CE12	Polar RS800	HSC “Rytm”	r	P	r	P	r	P
Mean RR (ms)	1008.74± 28.26	1009.63± 28.09	1009.14± 28.15	1,000	0.140	1,000	0.856	1,000	0.121
Mean HR (1/min)	60.73± 1.61	60.63± 1.59	60.68± 1.60	0,999	0.904	1,000	0.305	0,999	0.825
STD RR (ms)	74.37± 4.49	72.64± 4.35	74.37± 4.45	0,985	0.013	0,976	0.059	0,983	0.104
RMSSD (ms)	76.98± 6.67	74.82± 6.54	78.13± 6.47	0,991	0.014	0,949	0.113	0,954	0.104
pNN50 (%)	42.10± 4.05	41.09± 3.99	41.38± 4.05	0,998	0.002	0,999	0.003	0,998	0.327
RR tri index	12.31± 0.67	12.22± 0.57	12.33± 0.60	0,866	1.000	0,852	0.900	0,813	0.887
VLF (ms^2)	1046.72± 115.50	1057.94± 118.88	1040.23± 116.24	0,996	0.466	0,999	0.104	0,996	0.239
LF (ms^2)	1300.92± 226.27	1237.98± 220.30	1301.17± 225.98	0,956	0.837	1,000	0.723	0,956	0.641
HF (ms^2)	2321.54± 411.26	2238.02± 385.07	2316.46± 410.21	0,995	0.022	1,000	0.140	0,995	0.271
VLF (%)	27.80± 3.43	28.27± 3.38	27.64± 3.42	0,994	0.341	0,999	0.955	0,994	0.104
LF (%)	26.62± 2.64	26.19± 2.67	26.74± 2.65	0,971	0.070	1,000	0.004	0,972	0.723
HF (%)	45.51± 4.01	45.46± 4.04	45.56± 4.00	0,997	0.271	1,000	0.489	0,997	0.668
LF/HF ratio	0.76± 0.14	0.76± 0.14	0.76± 0.14	0,996	0.113	1,000	0.247	0,996	0.925
SD1 (ms)	54.60± 4.73	53.07± 4.64	55.42± 4.59	0,991	0.014	0,949	0.113	0,954	0.617
SD2 (ms)	88.36± 5.10	86.90± 4.87	88.42± 5.07	0,992	0.014	0,995	0.054	0,990	0.860

Note: HR – heart rate; STD RR – standard deviation of RR intervals; RMSSD – square root of the mean squared differences between successive RR intervals; pNN50 – percentage of successive intervals with a difference greater than 50 ms compared to the previous interval; RR tri index – the integral of the RR interval histogram divided by the height of the histogram; VLF, LF and HF – absolute (ms^2) or relative (%) powers from very low frequency, low frequency and high frequency bands respectively; LF/HF – ratio of LF to HF; SD1 and SD2 – from Poincaré plot the standard deviation perpendicular to or along to the line-of-identity respectively.

We found no statistically significant differences between the HRV indexes, calculated on the basis of RR time series, registered by Polar RS800 and SHC "Rytm" (see Table 4). As the result of CardioLab CE12 and SHC "Rytm" comparison, significant difference only in two indexes was revealed – the relative power of the low-frequency spectrum (LF) and pNN50. In the case of CardioLab CE12 and Polar RS800 comparison, the number of different HRV indexes was larger. Differences were found between some time-domain indexes (STD RR, RMSSD, pNN50) and the results of non-linear measurements (SD1, SD2). Correlation between HRV indexes was very high in all pairs of devices.

Discussion

Our study compared RR data and derived HRV indexes obtained from SHC "Rytm" and two other devices – ECG recorder CardioLab CE12 and Polar RS800. We found good agreement between time series of RR intervals, registered by SHC "Rytm" and ECG recorder. It is approved by the absence of significant difference in raw data ($P > 0.05$), high level of ICC (0.996) and comparatively low range of LoA (-22.89 – 22.54 ms). Calculated ICC level (0.996) was very close to the values of ICC (0.98–0.99) reported by other authors (Hernando et al., 2016; Nunan et al., 2008; Weippert et al., 2010) for ECG-Polar comparison. Our limits of agreement were wider than those reported by some authors (LoA in the range from –5.2 to 5.89 ms or –6.37 to 2.67 ms) in resting condition (Kingsley et al., 2005; Porto et al., 2009; Hernando et al., 2016; Cassirame et al., 2017). However, many authors revealed very close (-15.1 – 24.3 ms – Weppert et al., 2010; -12.76 – 11.16 ms – Gamelin et al., 2008), similar (-29.8 – 24.3 ms – Akintola et al., 2016; -22 – 25 ms – Nunan, 2008; -24.9 – 23.4 ms – Braga et al., 2016) or even higher (-60.5– 60.5 ms – Caminal et al., 2018) levels of LoA. Comparison of the individual cases found no significant differences in RR time series obtained by ECG recorder and HSC "Rytm" ($P > 0.05$) with the high correlation between data from two devices ($r = 0.97 \pm 0.02$). The correlation coefficients (0.97–1.00) were at the same range as those obtained by other authors (Caminal et al., 2018; Gamelin et al., 2006, 2008; Hernando et al., 2016; Nunan et al., 2009) during comparison of Polar devices and ECG recorders. Thus, on the basis of high ICC and correlation coefficient, absence of significant difference for RR intervals and narrow LoA, our results suggest very good agreement among the CardioLab CE12 and SHC "Rytm".

Our data also approved good agreement between the RR data of ECG recorder and Polar RS800, as reported by Hernando et al. (2016) for Polar RS800, Caminal et al. (2018) for Polar V800 and number of authors for Polar S810 (Braga et al., 2016; Cassirame et al., 2017; Gamelin et al., 2006, 2008; Kingsley et al., 2005; Nunan et al., 2008; Porto et al., 2009; Weippert et al., 2010). However, our LoA were larger, ICC – slightly lower (see table 2) and correlation coefficient – higher (see table 3) in the pair CardioLab CE12 vs HSC "Rytm", than in other cases. It is reasonable to suppose that repeatability of the data was the highest when comparing the ECG data to the HSC "Rytm".

In summary, our results clearly suggest that both the mean values and temporal changes in the time series of RR intervals, registered by SHC "Rytm", do not differ from those registered by the ECG systems (CardioLab CE12) and sport device with high level of accuracy (Polar RS800).

The HSC "Rytm" and ECG recorder displayed very high correlations between time, frequency and non-linear HRV indexes, similar to levels found in previous research with the Polar S810 (Gamelin et al. 2006, 2008; Nunan et al. 2009; Vanderlei et al. 2008). The similar high correlation coefficients were found during the comparison of HRV values from other pairs of devices. However, the difference in the values of two indexes (pNN50 and LF) was found between HSC "Rytm" and ECG recorder, and in five indexes (STD RR, RMSSD, pNN, 50SD1, SD2) – between Polar RS800 and ECG recorder. Previously poor agreement was found with the Polar S810 (Kingsley et al. 2004; Nunan et al. 2008), S810i and Suunto t6 (Weippert et al. 2010) and the RS800 (Wallén et al. 2012). The RMSSD and SD2 had previously been found to be significantly different from the ECG derived on by Gamelin et al. (2006, 2008) without the RR intervals correction. This pointed out the necessity of correction of the RR intervals, registered by HSC "Rytm", before the HRV indexes calculation.

To sum it up, the small level of deviation or HRV indexes from the "golden standard" ECG recorder (CardioLab CE12) data could be suggested for SHC "Rytm". However, the differences we have found revealed the necessity of application of some automatic correction algorithm in the SHC "Rytm".

Conclusions

The obtained data and the results of statistical analysis clearly suggest the absence of significant differences between the RR time series, registered by SHC "Rytm" and two other devices – ECG recorder CardioLab CE12 and Polar RS800.

No differences were found between HRV indexes derived from SHC "Rytm" and Polar RS800 data. We have found good agreement between the HRV indexes based on SHC "Rytm" and CardioLab CE12 data, although there are differences in two indexes. In order to improve the results we suggested elaboration and application of some automatic correction algorithm in the SHC "Rytm".

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