Lessons Learned: Heart Rate Variability Devices and Study Procedures

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Abstract:

Objective: This study aimed to compare heart rate variability metrics derived from four devices available at our Doctor of Chiropractic program educational institution.

Methods: Student and staff were recruited as study participants through campus electronic newsletters, flyers and in-course announcements. Eligibility requirements included non-smokers between the ages of 18-70 years with no known hypertension, chronic heart, or respiratory condition. Two electrocardiography and two photoplethysmography devices were used for data collection. Heart rate variability metrics derived from these devices included three time-domain and three frequency domain measures.

Results: Fifteen people responded to study recruitment efforts and met the eligibility requirements. However, data collection was only possible for three participants due to study interruption by the Covid-19 pandemic sheltering-in-place order. There was poor agreement for HRV metrics between the different devices. Variability was also noted within the same device/software system when two different investigators exported the Inter-Beat-Interval data and used different levels of artifact correction for the same volunteer participant.

Conclusion: This feasibility study identified several technical difficulties that can compromise heart rate variability measurements which should be considered for future research and by practitioners interested in the potential application of HRV within clinical and behavioral practice.

Keywords: Outcome Assessment, Health Care; Validation Study; Chiropractic

Introduction:

A primary focus of our doctor of chiropractic program (DCP) research effort is to explore chiropractic care within a healthcare continuum that focuses on health as defined by the World Health Organization “a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity.”(1) Our DCP research team is interested in surrogate outcome measures for overall health that may be evaluated and subsequently employed in research studies and clinical settings. One potential surrogate outcome measure is heart rate variability (HRV).

HRV quantifies the variation in time between heartbeats and is mediated by the parasympathetic division (including the vagus nerve) and the sympathetic division of the autonomic nervous system (ANS). (2) An optimal level of HRV may reflect the ability of the ANS to regulate the sinoatrial node of the heart and adapt the heart’s pace-making function to changing environments. (2, 3) Research suggests the rhythm of the heart’s afferent inputs to the brain then influences executive cognitive functioning, an important outcome for our DCP student population.(4-7) Specifically, vagally-mediated HRV is correlated with cognitive flexibility and cognitive inhibition.(8) HRV has also been shown to be a surrogate outcome measure for numerous diseases, including cancer, cardiovascular disease, and brain pathologies.(9-13) There are potential confounders to the associations between HRV and morbidity and mortality, however, including amount of time engaging in physical activity and lying down, both which can affect HRV and health outcomes. (3) Efforts to establish normative HRV values have found that HRV is also influenced by length of time data is collected, methods of data analysis, biological sex, age, and breathing patterns. (6)

It is important for chiropractic clinicians and researchers to understand more about how HRV is obtained and interpreted as recent studies have used electrocardiography (ECG) to obtain HRV data when assessing spinal manipulation interventions. (14-19) ECG devices use electrodes traditionally placed on the chest and/or limbs to detect the electrical activity of the heart. ECG devices are the gold standard for collecting HRV data but they are expensive and “tethered” units (connected via electrical cables) present particular difficulties during ambulatory activities. Recent advances in technology has seen the advent of Photoplethysmography (PPG) devices that use infrared light sensors to detect changes in blood volume in small capillaries in the finger or ear and may provide similar measurements as ECG.(20-23)

While PPG devices have been compared previously to ECG, we are not aware of studies specific to the PPG devices we have at our DCP, namely the INSiGHT neuroPULSE™ (Chiropractic Leadership Alliance. Las Vegas, NV) and emWave2 (Heart Math Institute. Boulder Creek, CA). The primary aim of this study was to evaluate the agreement between the ECG and PPG devices at our institution and the secondary aim was to assess their test-retest reproducibility.

Methods:

HRV measurement:

When we began this project in 2019, the inventory of HRV technology at our Doctor of Chiropractic Program (DCP) included four systems for recording and analyzing HRV data: a tethered ECG device (iWorx Technology (Dover, NH, USA)) which was housed in the physiology teaching lab for teaching purposes; and three HRV devices donated or acquired for the research lab, an untethered ECG Polar H10 (Bethpage, NY, USA) and two tethered PPG devices (Insight neuroPULSE™ and emWave2).

The iWorx Technology system uses ECG limb electrodes to detect the electrical activity of the heart and collect data on the Inter-Beat-Intervals (IBI). We selected iWorx, a priori, as our HRV reference standard since multi-lead electrode systems are the gold standard for recording HRV.(24) CLA INSiGHT was designed primarily for use in the chiropractic clinical office setting and uses PPG infrared sensors to detect the volumetric variations of blood circulation. The emWave2 assessment system is designed for clinic or home use and also relies on PPG sensors. The Polar H10 is frequently used in both home and research settings.(25) It collects HRV data using a single-channel ECG electrode sensor embedded in a chest strap.(26) While the iWorx, CLA INSiGHT and emWave2 technologies are all “tethered” systems with cables connecting their sensors to an amplifier/recorder, the Polar H10 system is untethered and transmits raw signal data to recording equipment wirelessly, via Bluetooth technology.

There are over 70 HRV metrics, including linear time-domain and frequency-domain measurements and non-linear measurements.(11, 24) Some HRV metrics, such as the time-domain root mean square of the successive differences (rMSSD) and the frequency-domain high frequency power (HF) are thought to reflect parasympathetic/vagal activity.(2) Other HRV metrics, for example the time-domain standard deviation of normal RR intervals (SDNN) and frequency-domain low frequency power (LF), are influenced by both parasympathetic and sympathetic activity.(2) For this study, we included the metrics that were available for each of the four HRV systems at our institution: the average interval between normal sinus node depolarization heart beats (AVNN) which is calculated by averaging the distance between R waves in normal QRS complexes and the rMSSD, SDNN, LF, HF and LF:HF ratio. The frequency-domain metrics can vary by their computation methods (parametric or non-parametric).(27) CLA INSiGHT and emWAVE2 include their own software to calculate these HRV metrics. The iWorx system and Polar H10 require external signal analysis. In this study, Kubios analytic software (Kuopio, Finland) was used to derive HRV metrics from the iWorx IBI data. Polar 10 was paired with its compatible software, Elite HRV (Asheville, NC, USA).

Study Recruitment and Feasibility study ethics approval and participant recruitment:

In this paper, we report the "lessons learned" from developing procedures for study of 2 technologies used in 4 devices for recording Heart Rate Variability (HRV). Members of the research team first evaluated the logistics of the setup and operation of the HRV technologies by collecting data on themselves, via 3 HRV devices that were concurrently attached to each participant:

- emWave2 - an ear-clip infrared sensor was placed on the left earlobe.
- CLA INSiGHT - participants placed three right hand fingers (index, middle, and ring) in a sensor/recording unit.
- iWorx ECG - electrodes were connected to participants in the "four-limb lead" configuration (both wrists and both ankles).

None of the three research team participants experienced pain or discomfort during data collection, providing a useful insight for drafting our Informed Consent document and our IRB application.

The Institutional Review Board of Life Chiropractic College West approved this study (PIDN 2019-005) to develop study procedures for recording HRV metrics derived from iWorx/Kubios; Polar10/Elite HRV; CLA INSiGHT; and emWave2 in a sample of healthy male and female adults ages 18-70. To establish requirements for statistical comparison of recorded HRV metrics across device/software systems, we calculated a priori that we would need a minimum sample size of 24 participants for a single-group, two-tailed test of differences in HRV measures ($\alpha = .05$; $\beta = .2$; and $r = .55$). An additional 10 participants were added to the recruitment target as an adjustment for anticipated participant attrition and data loss.

We recruited prospective participants via campus flyers, announcements in the campus weekly e-newsletter, and through our institution's research and public health classes. We used a screening instrument securely administered using Qualtrics ^{XM} (Provo, UT, USA) to identify eligible participants. Eligibility requirements included ages 18-70; no current cigarette use; no known hypertension, chronic heart, or respiratory conditions; not suffering from any mental disorders; and no use of beta blockers or anti-depressants as these are known to be possible confounders in HRV research (24). Participants were not given any incentives for participation.

Data collection:

Study participants were asked to wear loose clothing for their data collection visit and avoid: all food two hours before their visit; caffeine and moderate-intensity exercise the

morning of their visit; alcohol and vigorous-intensity exercise the day before their visit per recommendations in conducting HRV research.(24)

When study participants arrived at their appointment, they received details about the study and the investigators reviewed the informed consent. This took approximately 15 minutes. After completing the informed consent process, investigators assessed participants' compliance with the request that study participants avoid food, alcohol, and exercise prior to the data collection visit. Participants were then asked to use the restroom and turn off their cell phones before beginning data collection. The compliance checks and restroom visits added an additional 15 minutes to the time that we had anticipated for each data collection visit.

Each participant was asked to put on the Polar H10 chest strap that had been pre-moistened with a small amount of water to ensure electrical contact between skin and electrode sensor. It required 5-10 minutes to fit the Polar H10 strap and connect the iWorx instrumentation to a 4-Lead configuration on each participant's ankles and wrists. The EmWave2 sensor clip was then attached to the right ear of each participant and they were asked to place three right-hand fingers in the CLA INSiGHT device, as depicted in Figure 1.

Figure 1. Equipment connections for Heart Rate Variability (HRV) devices
a) CLA INSiGHT, b) emWave2 ear sensor (red circle), c) iWorx, and d) Polar H10 (green circle - ECG sensor).

For each participant, HRV data was collected concurrently from each of the four devices for seven minutes in both sitting and supine positions to ensure five minutes of usable data. Five minutes is a standard length of time for short-term HRV (as opposed to 24-hours for long-term HRV).(24, 27) Participants were asked to be still for a two-minute stabilization period before the five minute sampling. During data collection, participants were asked to breath at normal rates and remain still to optimize the quality of the data collected.(28) To increase participants 'comfort level, we placed a pillow beneath each participant's knees during supine data collection and offered jackets and blankets

because the exam room temperature was 66°F (18.9°C). Participants reported no pain or discomfort during data collection. After the data collection, we removed the equipment which took approximately five minutes.

Data integrity and security was maintained by collecting data offline on laptops stored in a locked room. Participant data was further protected by assigning each participant a random four-digit code which was used as the file names for collected HRV data.

Results:

The study announcement was well received by the campus community. Forty individuals expressed interest via email within a month, exceeding our recruitment goal of 34 people. Of the 40 respondents, 30 completed a screening questionnaire and 15 individuals met the study eligibility criteria and provided information for scheduling. We were able to collect data for three volunteers prior to the Covid-19 sheltering in place order.(29)

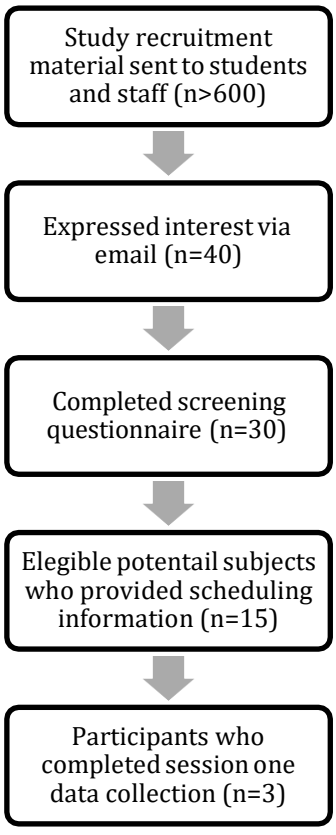

Figure 2: Flow chart of study recruitment and participation

Despite having practiced data collection several times previously on staff members, we experienced problems with the emWave2 and Polar H10 data for two volunteers.

Incorrect settings were initially used for saving the emWave2 and Polar H10 data. Additionally, the medium Polar H10 strap was too large for two participants and consequently the straps were cinched with medical tape to fit snuggly and securely around each participant's ribs to avoid movement artifacts.

Generation of the tachogram from the ECG recording of iWorx required manually placing horizontal cursors across the inter beat cycles to export the heart beat interval data into Kubios (Figure 2). The x-axis or the base of the ECG waves is considered as a baseline for the lower horizontal curser. When this baseline drifts or 'wanders' upwards or downwards then it is considered an artifact in the signal.(30) As demonstrated in Figure 3, a wandering baseline resulted in our losing heart beat interval data during the 5-minute data recording sessions for iWorx.2

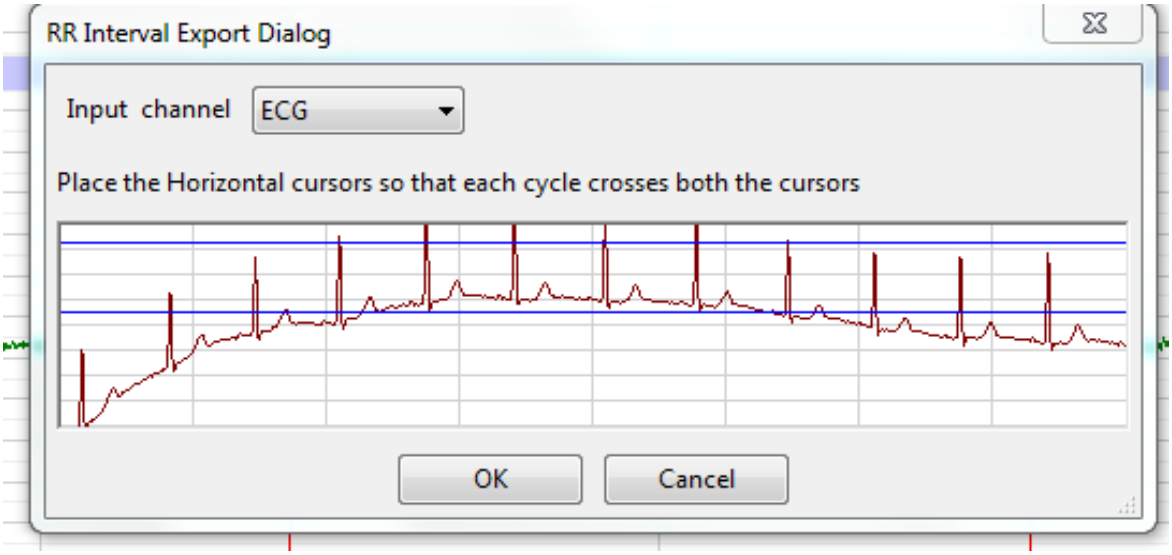

Figure 3: Screenshot of the wandering baseline in iWorx that caused some data to be lost when exporting inter beat data from iWorx to Kubios software for analysis. In this example, only the inter beat data between the two manually placed blue horizontal lines were exported.

For one participant, two investigators (an "Experienced Trainer" and a "Novice Trainee") independently set the horizontal cursors to export iWorx data for analysis in Kubios (Figure 2). Once the data was imported into Kubios, they used two different settings (uncorrected and very low correction) for the threshold by which the Kubios algorithm senses and removes artifacts. Uncorrected means no signal was filtered out. Very low correction means if there was more than a 450 millisecond interval between two heart beats, that data was removed.(31)

A comparison of iworx/Kubios data collected by the two investigators using two different artifact correction settings are displayed in Table 1. To protect the individual participant's data, instead of providing the raw HRV metrics, Table 1 highlights the difference between HRV metrics derived by iWorx/Kubios when the Experienced trainer exported the data and used very low artifact correction (Row A, Referent Group Ref) and the values derived from the Experienced trainer exported data with uncorrected values (Row B). In Row C, the difference is displayed between the Experienced Trainer export using very low correction (Ref) and the Novice Trainee using very low correction. These settings utilized the available data in an optimal manner.

Table 1: Differences in heart rate variability (HRV) metrics derived with iWorx/Kubios between two degrees of artifact correction and two examiners. Data from one participant, supine position

Device/Software	HR	AVNN	SDNN	rMSSD	LF	HF	LF/HF
A)iWorx export by Experienced Trainer and very low correction of artifacts in Kubios	Ref	Ref	Ref	Ref	Ref	Ref	Ref
B) iWorx export by Experienced Trainer and uncorrected artifacts in Kubios	-3	74	-802	-1258	-562967	-404954	-0.51
C) iWorx export by Novice Trainee and "very low" correction of artifacts in Kubios	-37	498	-343	-260	-295647	-38642	-5.26

Table Abbreviations: HR: average heart rate; AVNN: average interval between normal sinus node depolarization heart beats; SDNN: standard deviation of normal RR intervals (SDNN); rMSSD: root mean square of the successive differences; LF: low frequency power; HF: high frequency power; Ref: Reference data from which other values in the column were compared.

Since the exported data from iWorx was only a segment of the five-minute data collection period, we could not compare the HRV metrics between iWorx and the other three systems. We were therefore not able to standardize the time periods with the other systems which is why we did not include the iWorx data in Table 2. Table 2 shows the difference in values between Polar H10/Elite HRV (Referent group - Ref) and those derived from emWave2 (Row B) and CLA-INSiGHT (Row C) for one participant in the sitting position.

Table 2: Differences in heart rate variability (HRV) metrics derived from three devices concurrently on one participant, sitting position

Device/Software	HR	AVNN	SDNN	rMSSD	LF	HF	LF/HF
Polar H10/Elite HRV	Ref	Ref	Ref	Ref	Ref	Ref	Ref
emWave2	0	2	-6	-14	1693	1029	-2
CLA INSiGHT	-2	36	-73	-2570	-1787	-2862	1

Table Abbreviations: HR: average heart rate; AVNN: average interval between normal sinus node depolarization heart beats; SDNN: standard deviation of normal RR intervals (SDNN); rMSSD: root mean square of the successive differences; LF: low frequency power; HF: high frequency power; Ref: Reference data from which other values in the column were compared.

Per the study protocol, we scheduled all three volunteers to return the following week for a second day of data collection. Unfortunately, during this same week, the computer operating systems were switched from Windows 7 to Windows 10 by Informational Technology personnel without informing the research team. The iWorx and CLA INSiGHT station applications were not compatible with Windows 10, and this issue was not easily resolved. Further, all nonessential campus activities were halted during 2020, due to the Bay Area shelter-in-place order and response to the COVID19 pandemic. (29)

Discussion:

It is important to have valid and reliable tools for measuring baseline and outcome measures. As quoted by Leedy & Ormrod (2013) in the book “Measurement in Nursing and Health Research” by Waltz et al, “a research problem that employs faulty measurement tools is of little value in examining the problem under study.”(32) Our DCP community responded positively to research recruitment efforts to compare four HRV technologies and Qualtrics was a useful tool for screening potential research participants. Following are the lessons we learned from this study.

HRV recording systems (hardware devices and software) differ markedly in their portability, data acquisition requirements, data storage capabilities, data transfer capabilities, user-friendliness, learning curve, and algorithms for calculating HRV metrics. We discovered that tethered systems are cumbersome, especially when moving study participants between sitting and supine positions, and that at least two research staff are needed to properly run four devices and collect and save the data. Detailed, device-specific instructions with illustrations and a training and certification procedure are needed for all data collection personnel.

Systems that rely on the investigator to manually export the data and correct for artifacts introduce sources of measurement error which can bias the analytical results.(16) We had more variation in the HRV metrics collected between users and levels of artifact correction with iWorx combined with Kubios (Table 1) than we had between the three other devices (Table 2). Upon discussing the wandering baseline issue (Figure 2) with iWorx technicians and other HRV researchers, it was determined that possible causes were outdated software, old electrodes, and/or the iWorx was sensing the respiratory potentials superposed on the ECG signals.(30) While a wandering baseline should not affect measurement of the heart beat intervals, it does make it more difficult to export the RR intervals into the signal analysis software, Kubios. We also observed that "best practices" requires sanitizing non-disposable HRV system components after every use. This requires additional time between successive participants. Moreover, this increases the potential for sensor damage over time and consequently, increases budget cost projections.

The validity of the untethered Polar H10 device (and its predecessor H7) is supported by a body of evidence of published literature.(26, 33-36) In two studies with athletic participants, the correlation between rMSSD values derived from Polar H7/H10 and ECG system recordings in seated, resting conditions was .9 or above.(34, 35) A third study with 67 male participants ages 20-70 of various fitness levels reported high agreement of HRV metrics between the Polar H7 and ECG at rest however there was less agreement for participants who were older, had lower fitness levels, and greater percentage of trunk fat.(36) The authors concluded that phenotypic differences can cause disagreement between HRV recording devices. In our study, we also noted the importance of phenotype, given that different Polar H10 strap sizes are needed to accommodate research participants of various chest girths.

Since our study was initiated, we became aware of a published study comparing a 3-lead ECG system to the tethered emWave2 device.(37)This study found in 14 healthy adults ages 20-48 that the tethered emWave2 device tended to yield larger SDNN and RMSSD values and lower LF/HF ratios than the 3-lead ECG system. The authors noted that emWave2 had greater susceptibility to motion artifact and there was more lost data from the emWave2 device compared to the ECG system. Otherwise, the authors reported valid and reliable measurements between emWave2 and the 3-lead ECG.(37)

Due to issues with software and a global pandemic, our study was stopped after collecting one session of data from three participants. The small sample size and inability to collect follow-up data precluded any statistical analyses and inferences about the validity and reliability of the four technologies used to collect HRV data. An additional concern is the close proximity of electrical equipment to our research room which emitted 60-Hz electrical noise that could have also compromised the electrophysiological signals in HRV devices that we tested.

Conclusion:

It is imperative for HRV research to have valid and reliable data collection and processing procedures established for the population that will be included in the research. This feasibility study identified several technical difficulties that can compromise heart rate variability measurements which should be considered for future research and by practitioners such as chiropractors who may be interested in the potential of HRV for informing clinical or behavioral practices and “wellness care”. In this small study, we identified many technical difficulties that compromised HRV measurement, and we continue exploring the battery of HRV instrumentation for the advancement of our institutional educational and research objectives.

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