

Digital Ballistocardiography for the Assessment of Cardiac Timings in Adults

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Abstract

Introduction: Cardiovascular disease is a leading cause of death worldwide. Currently, the electrocardiograph (ECG) and echocardiograph (ECHO) are the clinical tests of choice for assessing heart disease; however, the ECG only assesses the heart's electrical activity, while ECHO is expensive, time consuming and not readily available. Modern accelerometer-based technology is revitalizing the science of ballistocardiography, allowing the motion of the heart to be captured in a quick, efficient and cost effective way. **Methods:** We examined the feasibility of the digital ballistocardiograph (dBG300™) to assess cardiac timings in healthy adults in a clinical setting. Seventy-two participants (36 men and 36 women aged 18 years and above) had a dBG300™ waveform collected on one occasion. The waveform was annotated for mitral valve closing (MVC), aortic valve opening (AVO), aortic valve closing (AVC), and mitral valve opening (MVO). Isovolumetric contraction time (IVCT) and isovolumetric relaxation time (IVRT) were calculated. Summary statistics were calculated for all cardiac timings. **Results:** Average cardiac timings were: MVC, 54 ± 11 ms and 52 ± 10 ms; AVO, 98 ± 12 ms and 94 ± 13 ms; AVC, 418 ± 27 ms and 425 ± 31 ms; MVO, 511 ± 29 ms and 518 ± 33 ms; IVCT, 43 ± 9 ms and 42 ± 8 ms; and IVRT, 93 ± 10 ms and 93 ± 9 ms, for men and women, respectively. The dBG300™ was easy to administer and interpret, and data collection took less than 5 minutes. A satisfactory recording was obtained in all 72 participants. **Conclusion:** The dBG300™ can quickly and effectively assess cardiac timings in healthy adults. The dBG300™ presents a significant opportunity to improve the assessment of patients with suspected heart disease.

Keywords: Ballistocardiogram · Valve Timings · Heart Disease · dBG300™

Introduction

Cardiovascular disease is a common problem and is the cause of more deaths in the Western world than all other forms of disease¹. In the USA, heart disease is the leading cause of death (26% of deaths per year²), and cost the USA \$316.4 billion in health services, medications and lost productivity in 2010¹. In Europe, heart disease accounts for 48%

of deaths per year, and costs the European Union €192 billion per year in direct health care costs³. Therefore, technologies that can improve the assessment of, or aid in the detection of, heart disease are vital for disease prevention, patient monitoring and overall patient care. Currently, devices such as electrocardiograph (ECG) monitors and echocardiographs (ECHO) are

used in the identification and assessment of heart disease⁴. The ECG, although a relatively quick test, provides only an electrical assessment of the heart. It does not provide information concerning the force of the heart's contraction⁵. An ECHO, while providing accurate and direct 2D and 3D images of the heart for assessment of cardiac timings and volumes, requires a highly trained ultrasound technician to obtain the image and an echocardiologist for image interpretation. It is therefore expensive, time-consuming and not generally available for the regular monitoring of patients⁴. These technology limitations have profound implications for regular patient assessment and highlight the need for a device that can assess cardiac events (electrical and mechanical) quickly, regularly and inexpensively.

The science of ballistocardiography (BCG) was conceived over a century ago^{6,7}. Although conceptually attractive, BCG was limited in practice as devices were cumbersome and required fixed installation. This made BCG difficult and impractical to use on a large scale, and it was abandoned in the 1970s. Today, modern accelerometer-based technology is revitalizing the science of BCG, allowing the motion of the heart to be captured and used in the assessment of cardiac function^{8,9}. We have applied recent advances in hardware and software technologies (specifically tri-axial accelerometers) to capture non-invasively the low-frequency vibrations created by cardiac contractions, using a device called the digital ballistocardiograph (dBG300™). The dBG300™ is a small, portable device that allows simple assessment of cardiac events and the force of the heart's contraction in less than 5 minutes. The dBG300™ is inexpensive, requires minimal training and lends itself to regular patient monitoring and assessment on a large scale. The purpose of the current study was to evaluate the feasibility of the dBG300™ to assess cardiac timings in healthy adults in a clinical setting.

Materials and Methods

Participants

Seventy-two non-smoking (for at least 6 months prior to study start) adults, with a body mass index between 18.5–29.9 kg/m² were recruited for this study (36 men and 36 women, aged 18 year or older). All participants were healthy according to medical history, 12-lead ECG (PQ or PR interval ≤ 210 ms), blood pressure (systolic blood pressure 100–140 mmHg inclusive; diastolic blood pressure 60–90 mmHg inclusive), resting heart rate (50–99 beats per minute inclusive), resting respiratory rate (12–20 breaths per minute inclusive), resting body temperature (35.8–27.5°C inclusive), and a negative cotinine urine test. Participants were excluded if they had a known history or presence of any clinically significant hepatic, renal, gastrointestinal, cardiovascular, pulmonary, endocrine, immunological, musculoskeletal, neurological, psychiatric, dermatological or hematological disease or condition; presence of illnesses within 30 days prior to the study; presence of any significant physical or organ abnormality including pectus excavatum, pectus carinatum or other chest abnormalities, including a scar in the sternum area; a known history of alcohol or drug abuse, severe allergic reactions, asthma, or sleep disorders; had used prescription medication within 14 days or over-the-counter medication within 7 days prior to study start (except hormonal contraceptives); had undergone major surgery within 6 months prior to study

start; or were pregnant (a positive hCG test). All participants were asked to fast for at least 1 hour prior to testing. Water was allowed *ad libitum*, except during measurement.

All participants at the time of measurement were enrolled in the Heart Force Medical Inc. ECHO2 clinical trial. ECHO2 is a cross-sectional clinical trial aimed at comparing cardiac timings measured by the dBG300™ to those obtained using a commercially available echocardiograph. The study was approved by Optimum Clinical Research Inc. Ethics Review Board (BPSI1301) and all participants provided written informed consent prior to taking part in the study.

The Digital Ballistocardiograph

The digital ballistocardiograph (dBG300™, Heart Force Medical Inc., Vancouver, Canada) consists of three main components: the sensor, the digitizing transceiver unit, and the proprietary software application used for device control and data analysis (Figure 1A). The sensor captures both the seismic vibrations generated by the heart's motion and a recording of the heart's electrical activity during

each cardiac cycle (each heart beat). The vibrations, or forces, are detected using high sensitivity tri-axial accelerometer-based technology aligned to the three principal anatomical axes. These vibrations are processed digitally and displayed, with the acceleration amplitudes as the vertical axis and time as the horizontal axis. The forces are captured in three waveforms, one for each anatomical axis, and are the basis of the dBG300™ waveform. The transceiver unit digitizes and transmits the captured data via a secure Bluetooth™ connection to the application software hosted on a personal computer. All data are displayed on a computer screen and proprietary software provides tools for annotation and analysis of the waveforms (Heart Force Medical Inc.). Acceleration is expressed in milli-gravity (mG) units and time is recorded in milliseconds (ms). A single, non-diagnostic ECG is sensed, recorded, and displayed synchronously with the dBG300™ waveform using a rhythm strip configuration similar to a single-lead ECG (lead 1). The dBG300™ has obtained US Food and Drug Administration (US FDA) approval for use in

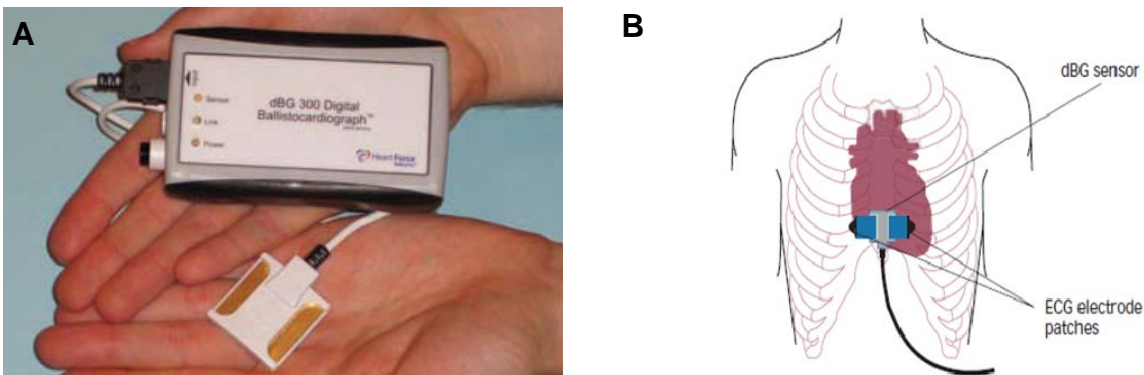


Figure 1. A) The digital ballistocardiograph sensor and transceiver; B) Digital ballistocardiograph sensor placement. Abbreviations: dBG (digital ballistocardiograph), ECG (electrocardiograph).

measuring cardiac cycle timings events, with US FDA agreement that the dBG300™ is substantially equivalent to echocardiography in the measurement of cardiac timing events (unpublished data).

Digital Ballistocardiograph Recordings

Participants were asked to lie still on an examination table, in a supine position, with their hands and arms at rest beside the body. Participants were asked to retain a normal breathing pattern and instructed not to make sudden movements or noises, and not to talk or cough while the dBG300™ waveform was being collected. Participants were asked to expose the sternum area of their chest for sensor placement. The sternum area needs to be smooth, flat and free of hair for adequate sensor placement so some participants required a small area on the chest to be shaved. This was completed using standard shaving cream and manual razors. The sternum area was cleaned using alcohol wipes (70% isopropyl) and left to air dry prior to sensor placement.

A trained operator administered the test using a dBG300™ (Heart Force Medical Inc.). The dBG300™ waveform was obtained using a proprietary sensor (Heart Force Medical Inc.) placed on the sternum in the midline, with the lower edge of the sensor placed approximately 3cm above the xiphoid process (Figure 1B). Two ECG electrodes were used to affix the sensor and provide the required skin contact. A 30-second dBG300™ recording was obtained and transmitted via Bluetooth™ to a computer for annotation of the waveform by proprietary software (Heart Force Medical Inc.). If the participant moved, talked or coughed during the test, the test was repeated.

Data Annotation

We annotated mitral valve closing (MVC), aortic valve opening (AVO), aortic valve closing (AVC) and mitral valve opening (MVO) on the dBG300™ waveform. We calculated isovolumetric contraction time (IVCT) as the difference between MVC and AVO, and isovolumetric relaxation time (IVRT) as the difference between MVO and AVC. Valve timings were calculated from Q on the ECG wave. All cardiac timings are reported in milliseconds (ms) and were averaged from 10 consecutive heart beats annotated from the 30-second dBG300™ waveform.

Reproducibility

In a previous study, we determined *in vivo* within-participant and intra-/inter-operator precision for the dBG300™ measurements. We assessed 9 healthy participants (males aged 38 ± 7 years) 3 times without sensor repositioning (within participant) and 2 times with sensor repositioning (intra and inter operator). Precision was calculated as the root mean square error coefficient of variation (RMSECV, %) and was less than 4% (within), 8% (intra) and 10% (inter) for all cardiac timings.

Statistical Analysis

We calculated descriptive statistics for the cardiac timings in males and females. A *t*-test was used to assess differences in cardiac timings between males and females (alpha set at $P < 0.01$). We assessed all cardiac timings as adjusted (for heart rate) and unadjusted (no adjustment for heart rate) to assess the impact of heart rate on the variables measured. Using adjusted or unadjusted data did not significantly impact the cardiac timings and therefore

we present unadjusted cardiac timings only. STATA (STATAIC, Version 11.0, StataCorp LP, TX, USA) was used for all analyses.

Results

We provide participant characteristics and cardiac timings in Table 1. As expected, males were significantly taller and heavier than females ($P < 0.01$); however, there were no significant differences for any of the cardiac timings between males and females ($P > 0.01$).

The dBG300™ was easy to administer and interpret with minimal training required. Participant set-up and dBG300™ waveform collection took less than 5 minutes. Annotation of each waveform took a few minutes. A clean dBG300™ recording was obtained in all 72 participants. Only 9 (12%) participants required a repeat test: 7 due to unacceptable ECG recordings or Bluetooth™ failure and 2 due to the participant talking and/or moving during the test. The whole procedure took approximately 5 minutes for participants who required a

repeat test. Averaging the cardiac timings over 10 consecutive heart beats reduced the baseline noise, but all components of the waveform were visible for each heart beat.

Discussion

This study shows that it is feasible to use the dBG300™ to assess cardiac timings in healthy adults in a clinical setting. It also provides pilot ranges for the dBG300™ cardiac timings. It has been known for some time that cardiac timing intervals provide valuable mechanistic and diagnostic insight into systolic and diastolic heart function, with any disturbance in normal cardiac physiology, mechanics and hemodynamics resulting in shortened or delayed cardiac time intervals¹⁰. Studies since the 1950s have shown the value of ballistocardiographic assessment of cardiac timings in 1) the diagnosis of ischemia and angina¹¹, coronary artery disease^{12, 13}, congenital heart disease¹⁴ and myocardial infarction¹⁵⁻¹⁷; 2) the assessment of ejection fraction¹⁸ and bi-

Table 1. Descriptives and dBG300™ cardiac timings (mean ± SD) for all participants.

	Males ($n = 36$)	Females ($n = 36$)	Overall ($n = 72$)
<i>Descriptives</i>			
Age (years)	45.8 ± 15.0	48.2 ± 16.5	47.0 ± 15.7
Height (cm)	173.2 ± 6.2 *	160.1 ± 7.5	166.6 ± 9.5
Body Mass (kg)	78.6 ± 8.3 *	65.4 ± 9.3	72.0 ± 11.0
<i>Cardiac Timings</i>			
Mitral Valve Closing (ms)	54 ± 11	52 ± 10	53 ± 11
Aortic Valve Opening (ms)	98 ± 12	94 ± 13	96 ± 12
Aortic Valve Closing (ms)	418 ± 27	425 ± 31	421 ± 29
Mitral Valve Opening (ms)	511 ± 29	518 ± 33	515 ± 31
Isovolumetric Contraction Time (ms)	43 ± 9	42 ± 8	43 ± 9
Isovolumetric Relaxation Time (ms)	93 ± 10	93 ± 9	93 ± 10

* Males significantly different from females ($P < 0.01$).

ventricular pacing efficacy during device implantation¹⁹ and 3) identifying cardiac resynchronization responders and non-responders²⁰. Until now, however, it has not been simple, quick or inexpensive to assess such timing intervals on a large scale. The dBG300™ represents a significant improvement compared with the ballistocardiograph technology that was offered to cardiologists in the 1950s²¹ and again in the 1990s²², and provides an opportunity for large-scale use.

Current guidelines outline the use of ECHOs and magnetic resonance imaging (MRI) as diagnostic procedures in the detection, management and prevention of cardiovascular disease states^{5, 23, 24}. However, ECHO and MRI methods are expensive, the assessments are lengthy (generally 30 minutes or longer), and both require specialized technicians and, more often than not, return visits for the results. In comparison, the dBG is portable and easy to use, requires limited training and technical support to operate in a busy clinical setting; and results are immediately available, freeing the patient from a return visit to the physician. The dBG does not provide an image of the heart, but previous studies suggest an image is not required for accurate measurements of timing events in the cardiac cycle²⁵. Indeed, we have previously shown the dBG300™ to be substantially equivalent to echocardiography in the measurement of cardiac timing events²⁶.

In summary, the dBG300™ is a feasible method to assess cardiac timings in healthy adults. Given the importance of heart disease prevention and regular monitoring of patients with heart disease, the dBG300™ presents a significant opportunity to improve patient care. Future research is needed to

assess the use of the dBG300™ in a range of clinical and non-clinical situations and disease states in order to assess its true medical capabilities for both clinicians and patients.

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Conflicts of Interest

All authors are employees of Heart Force Medical Inc.

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