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Defining the physiological bounds of left ventricular ejection time with a wireless, wearable ultrasound: An analysis of over 137,000 cardiac cycles

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Abstract

Background: Flow time (FT) or the left ventricular ejection time (LVET) is the duration of mechanical systole, when the aortic valve is open and ejecting blood. LVET can be measured in the common carotid artery from the time of the systolic upstroke to the incisural notch. FT is directly related to stroke volume (SV) and therefore has important implications for inpatient and outpatient cardiovascular care. Despite this known relationship between FT (i.e., LVET) and SV, large patient datasets describing the distribution and physiological bounds of FT are lacking.

Methods: Using a wearable, continuous-wave Doppler ultrasound patch, we are amassing a database of cardiac cycles from the common carotid Doppler pulse in patients and healthy volunteers performing various preload challenges.

Results: From this dataset of over 137,000 measurements in 347 patients, we report the mean and distributions of the common carotid artery flow time (i.e., LVET) corrected for heart rate using several prevailing equations.

Conclusions: Our findings are the most extensive exploration of the physiological bounds of FT (i.e., LVET) and are useful in both clinical assessments of cardiac health and various algorithm detection applications.

Keywords

Left ventricular ejection time, corrected flow time, carotid artery, Doppler ultrasound, wearable technology, functional hemodynamic monitoring, fluid responsiveness

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Introduction

The duration of mechanical systole (i.e., flow time, FT, or left ventricular ejection time, LVET) has been a measure of interest for well over a century.[1,2] Prior to readily-available transthoracic echocardiography (TTE), FT was combined with other measures to non-invasively assess cardiac function.[3] Though this avenue of study was largely abandoned with the increasing accessibility of TTE, the rise of point-of-care ultrasound (POCUS) has renewed clinical interest in FT.[4–6]

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While there are multiple determinants of FT, two key factors are the heart rate (HR) and stroke volume (SV).[5,6] Accordingly, when a hemodynamic intervention is performed, change in FT reflects both cardiac cycle length (i.e., HR) and the volume of left ventricular ejection (i.e., SV). To mathematically isolate SV, a number of equations are used to correct for HR; the two most common are those of Wodey and Bazett.[4,5,7–9] Previous investigators have shown a direct relationship between HR-corrected FT/LVET and SV using a variety of reference standards including indicator dye dilution,[2,10] pressure gradient technique,[11] intrapulmonary thermodilution via pulmonary artery catheterization and trans-pulmonary thermodilution-calibrated pulse contour analysis,[12–14] bioreactance,[4] invasive and non-invasive, uncalibrated pulse contour analysis,[15–18] as well as ascending aortic Doppler ultrasound.[19,20] Given this relationship, HR-corrected FT/LVET is used to measure the effect of intravenous (IV) fluid in the emergency department, intensive care unit and operating room.[4,12,15,21–23] Furthermore, corrected FT/LVET has been used to gauge the efficacy of inpatient and outpatient heart failure (CHF) therapy in patients with systolic dysfunction[24–26] and falling FT is an independent risk factor for incident CHF.[27]

When FT is measured at the common carotid artery and corrected for HR (ccFT), its change is used to infer SV change.[4,5,16–21] Importantly, this data can be captured via a novel, wireless, wearable Doppler ultrasound patch worn over the common carotid artery which could have future use for monitoring cardiovascular therapy in the inpatient and outpatient settings.[28–31] As we conduct on-going clinical studies with this device, we are amassing hundreds of thousands of cardiac cycles in both volunteers and patients. From this dataset, we report the physiological bounds of the ccFT across a range of healthy controls and patients, both at rest and undergoing preload modification of some form. The importance of collecting and reporting this data is to guide further study of the ccFT for our group and others, highlight the clinical differences between correction equations and help direct algorithm development.

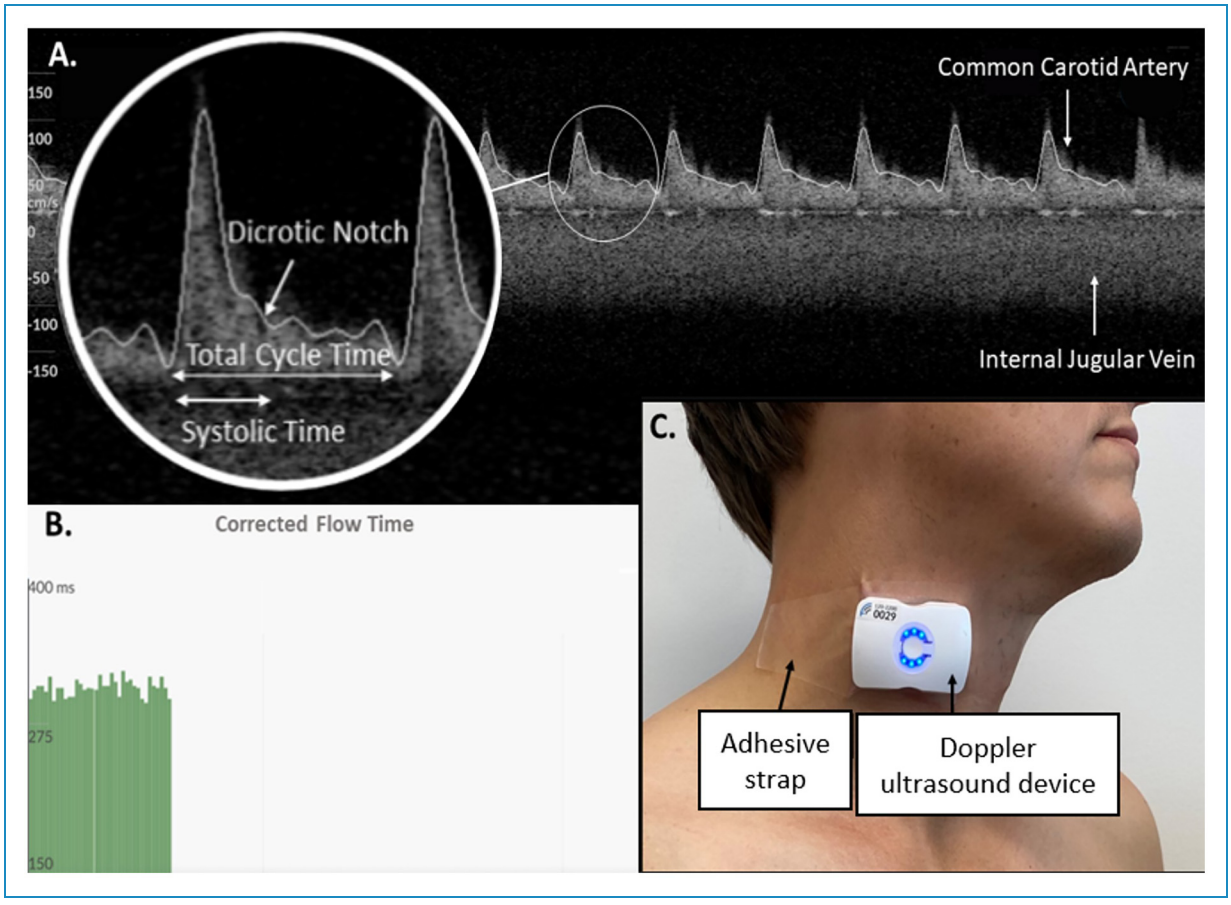

Figure 1. Overview of wearable Doppler ultrasound device and interface used for data collection. (a) Example of carotid Doppler spectrogram and features used to calculate ccFT values (inset) (b) ccFT values calculated per cardiac cycle on device interface. (c) The wearable Doppler device adhered to the neck of a sample patient.

Methods

This report is based on a secondary analysis of previously collected, anonymized data. All data collection was initially performed after approval of the local Institutional Ethics Committee at the Northern Ontario School of Medicine, University of California Los Angeles, Northwell Health Long Island, Eastern Health St Johns Newfoundland, Mayo Clinic and OSF Saint Francis Medical Center, Peoria. At all sites, only adult patients were included. Exclusion criteria were known, severe (> 60%), bilateral carotid artery stenosis, inability to cooperate with a hemodynamic intervention, known severe aortic or mitral valve disease, receipt of more than 500 mL of IV fluids prior to ultrasound assessment or failure to provide written and informed consent at the time of enrollment. The wireless, wearable Doppler ultrasound patch used to collect data is shown in Figure 1 along with elements of the corresponding graphical user interface. The features of the carotid Doppler spectrum used to calculate the ccFT are shown in Figure 1(a). The ccFT is calculated for each cardiac cycle and displayed as shown in Figure 1(b). In all subjects, the common carotid Doppler pulse was detected by the displayed spectrogram and audible Doppler shift consistent with the common carotid artery. Once obtained, the wearable device was adhered in place as shown in Figure 1(c).

Anonymized carotid Doppler assessments from our dataset were included. An assessment was specified as any continuous recording on an adult healthy volunteer or patient, consisting of either constant monitoring with no external changes or an event resulting in a defined increase or decrease in preload. The changes in preload could have been induced by lower body negative pressure, passive leg raise, gravitational positional change (e.g., Trendelenburg) or a rapid fluid challenge. To determine the flow time, eight qualified experts labeled the start and stop of mechanical systole defined as the upslope of systolic ejection and the dicrotic notch, respectively.

The corrected flow time from all included cardiac cycles was measured via the equations of Wodey, Bazett, Fredericia and Weissler[5] (see equations 1–4 below). From this, descriptive statistics for all equations were calculated. The data was further parsed into healthy volunteers versus patients and the hospital departments in which the patient recordings were made. Data was also divided based on the prevalence of irregular beats using an automated irregularity detection algorithm. A patient was determined to exhibit irregular beats when more than 25% of beats have a rolling peak-to-peak coefficient of variation above 20%. Visual inspection was then used to validate the determination of irregularity. Furthermore, given that sex-related cardiovascular differences[32] are known to occur with absolute LVET[2,33] we analyzed the data dichotomized as men versus women. A Mann-Whitney U test was used to determine sex differences for each equation. Clinically relevant comparisons between average patient ccFT by equation (pairwise) across departments were conducted using a non-parametric 4-way test (Kruskal-Wallis). We corrected for multiple comparisons using a Bonferroni correction; alpha was set at 0.01. Within patient ccFT is described and the coefficient of variation across equations is compared by using the Levene test. Finally, the data was dichotomized based on regular versus irregular cardiac rhythm and is described.

$$\mathrm{ccFT}_{\mathrm{Wodey}} = \mathrm{Flow\ Time} + 1.29 * (\mathrm{Heart\ Rate} - 60) \quad (1)$$

$$\mathrm{ccFT}_{Bazett} = \mathrm{Flow\ Time} * 1/\sqrt{60/\mathrm{Heart\ Rate}} \quad (2)$$

$$\mathrm{ccFT}_{Fredericia} = \mathrm{Flow\ Time} * 1/\sqrt[3]{60/\mathrm{Heart\ Rate}} \quad (3)$$

$$\mathrm{ccFT}_{Weissler} = \mathrm{Flow\ Time} + 1.60 * (\mathrm{Heart\ Rate} - 60) \quad (4)$$

Table 1. Healthy volunteers and patient characteristics.

Number of patients	347
Female sex, n (%)	144 (41%)
Sex unknown, n (%)	22 (7%)
Age, mean (SD)	64 (18)
Age unknown, n (%)	74 (21%)
Heart rate, mean (SD)	82 (22)
Heartbeat Regularity Regular and irregular heartbeats were determined based on an automated irregularity detection algorithm.	
Regular, n (%)	325 (94%)
Irregular, n (%)	22 (6%)
Regular, heart rate, mean (SD)	85 (23)
Irregular, heart rate, mean (SD)	99 (35)
Department evaluation completed in	
Emergency Department, n (%)	170 (49%)
Outpatient, n (%)	79 (23%)
Intensive Care Unit, n (%)	7 (2%)
Operating Room, n (%)	34 (10%)
Healthy, n (%)	57 (16%)

Results

The characteristics of all subjects are listed in Table 1.

The descriptive statistics for all cardiac cycles and all equations are presented in Table 2, Figure 2, and within patient means in Table 3. Further, the mean and standard deviations for each equation are shown for the ccFT as parsed into males versus females, regular versus irregular cardiac rhythm, and healthy volunteers versus patients and their location of recording (i.e., hospital department location).

Table 2 and Figure 2 demonstrate a range of ccFT that falls between 100 and 500 ms for all equations under varying physiological conditions. No significant difference between regular and irregular rhythmic cycles was found. Fredericia's equation revealed significant differences between patients across departments ($p < 0.01$), while other equations were not as sensitive to such groupings. Further, males had significantly lower ccFT than females ($p < 0.01$), and those in the Emergency Department appeared to vary significantly in average ccFT dependent on equation ($p < 0.01$). Figure 2 highlights the close relationship between equations wherein averages are between 302 and 312 ms and is overrepresented by ccFT below the average; this is evident in the negative skewness of each equation's distribution (Table 3). The sharp peaks indicated by the leptokurtic shapes of the ccFT distribution are evident across all equations and a coefficient of variation of around 6–7% (Figure 2, Table 3). Finally, there was no significant difference in within patient coefficient of variation based on equation ($p = .15$).

Discussion

In this brief research correspondence, we report the largest known descriptive evaluation of the common carotid artery corrected flow time which is a surrogate for left ventricular ejection time.[34] We believe that these data are clinically and technically important as they provide normal limits for a relatively large number of subjects across a variety of clinical settings; as clinicians often couch physiological data in these terms, our results help define the FT or LVET corrected for heart rate in clinical practice, considered below. Additionally, our data are important for algorithm development such as outlier rejection. As mentioned, the mean and standard deviation range of the four equations cover

Table 2. ccFT average values ± 3σ. Range Calculated by various equations - split by regular and irregular heart rhythms, and by department of patient evaluation – μ ± 3σ [ms].

Equation	Wodey	Weissler	Bazett	Fredricia*
Total (n = 136,339/137,521 cardiac cycles (99.14%)) (i.e., includes only cycles ≤250BPM with valid ccFT)	301.46 ± 104.28	309.51 ± 101.77	311.20 ± 121.46	295.49 ± 125.81
Females (n = 55,376 cardiac cycles)	306.16 ± 107.49	314.49 ± 106.93	317.48 ± 127.05	300.79 ± 128.49
Males (n = 66,846 cardiac cycles)**	299.92 ± 101.68	307.52 ± 98.25	308.32 ± 114.99	293.73 ± 121.76
Heart Beat Regularity				
Regular Heart Rhythmic Cycles (n = 128,840)	302.43 ± 101.95	310.23 ± 98.78	312.54 ± 117.24	297.09 ± 122.27
Irregular Heart Rhythmic Cycles (n = 7499)	284.83 ± 128.57	297.03 ± 138.51	288.23 ± 164.35	267.97 ± 153.90
Patient Department or Healthy Volunteer				
Emergency Department* (n = 60,062)**	297.52 ± 113.63	309.84 ± 113.67	308.59 ± 137.63	285.68 ± 138.59
Outpatient (n = 15,337)	302.01 ± 101.89	304.89 ± 100.12	307.14 ± 106.15	300.98 ± 105.71
Intensive Care Unit (n = 2999)	286.30 ± 96.15	295.22 ± 94.46	295.15 ± 126.03	278.48 ± 126.66
Operating Room (n = 10,039)	296.61 ± 139.93	299.56 ± 138.24	300.87 ± 144.61	294.87 ± 144.65
Healthy (n = 47,902)	308.18 ± 77.47	313.54 ± 70.68	318.94 ± 90.78	307.22 ± 97.08

*Indicates differences between average patient ccFT by a department for one equation, $p < .01$.
**Indicates differences between males and females for each equation, $p < .01$.
***Indicates differences between average patient ccFT by equation for one department, $p < .01$.

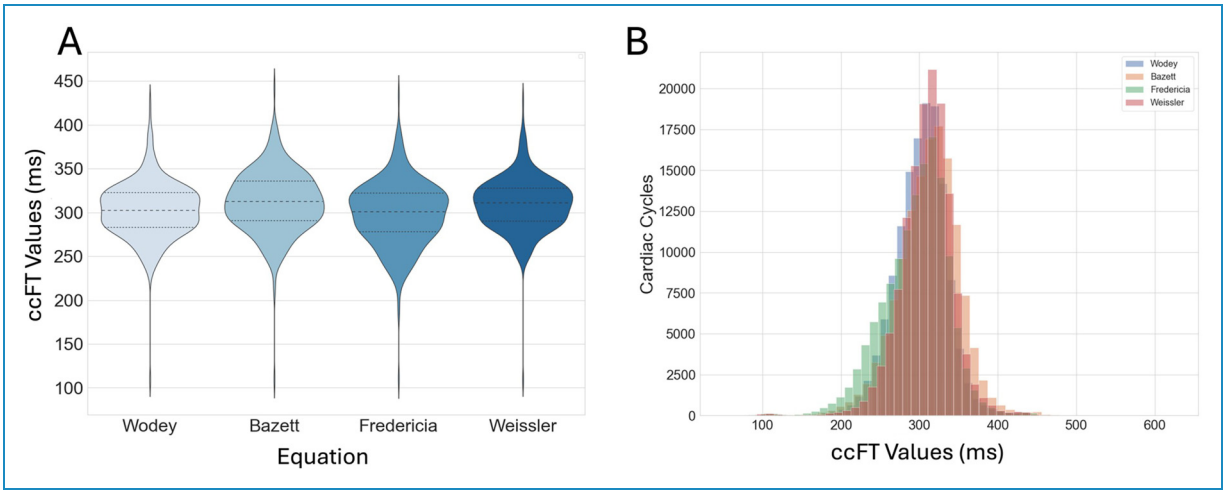

Figure 2. Violin plot overlaying boxplot showing average ccFT across patients by equation (a), and histograms (b) represent the distribution of all ccFT value by equation.

Table 3. Within patient ccFT descriptive statistics for cardiac cycles with ≤250BPM, n = 136,339 (99.14% of all cycles).

Statistic (Means)	Wodey	Bazett	Fredericia	Weissler
Mean (± 3σ)	302.96 ± 94.56	311.87 ± 104.79	298.35 ± 110.55	309.75 ± 90.96
Median	302.55	312.39	300.84	310.7
25% Percentile	283.23	290.60	277.74	290.18
75% Percentile	322.86	335.77	322.19	327.80
Skewness	−0.27	−0.39	−0.34	−0.49
Kurtosis	4.4	3.11	1.96	5.64
Coefficient of Variation	7.02	6.72	6.13	6.07

approximately 99.5% of the values with a 0.5% range of outliers. These outliers were found to be singular cardiac cycles in patients with physiologies such as extreme tachycardia, which were uncommon in our data set. Thus, including outliers as seen in Figure 2, we conclude that a ccFT less than 100 ms or greater than 500 ms is likely to be an erroneous value rather than physiological reality in patients and healthy volunteers.

Our data are comparable with previous investigations in both critically-ill patients,[4] those undergoing elective surgery,[17,18,35] and healthy, outpatient volunteers undergoing passive leg raising.[7–9] Other authors observed that Bazett's equation gives values roughly 10 ms greater than that of Wodey, similar to the results herein. We have previously observed no significant diagnostic difference between Wodey and Bazett for detecting a 10% SV change in healthy volunteers[5]; thus, the algorithm in the wearable Doppler used for this study utilizes Wodey's equation. Across all equations, the average ccFT trends lower amongst patients in the intensive care unit – significantly so using Fredericia's method. This is also seen when accounting for sex differences. If the ccFT is a crude approximation of SV, this makes some sense given that critically-ill patients are most likely to have hemodynamic derangement (e.g., low SV). Further, LVET or ccFT variability can impact the sensitivity of detecting changes in SV in diagnostic settings. Although we found no difference based on equation, variability can influence signal-to-noise ratio and sample size requirements, where higher variability necessitates averaging across more cardiac cycles to confidently detect small effect sizes.

Given the established relationship between SV and LVET or ccFT,[2–20] there are practical, clinical applications of the systolic duration that deserve brief mention. First, in

the ICU, changing ccFT or LVET can infer SV response to therapy (e.g., IV fluid), also known as 'preload responsiveness' (PR). PR is a 10–15% increase in SV following IV fluids.[36,37] Data from randomized,[38] observational[39] and association[40] studies reveal that dosing IV fluid based on PR improves patient-centered outcomes (i.e., reduces the risk of mechanical ventilation, renal replacement therapy and health-care costs). Indeed, one health system has incorporated ccFT into a sepsis-specific resuscitation algorithm.[23] Second, both inpatients and outpatients with left ventricular dysfunction have diminished flow time[24,25,41] that improve with therapy and falling LVET over time is associated with incident CHF.[27] Therefore, monitoring ccFT or LVET might predict worsening CHF and direct therapy based upon existing literature.

Our study does have limitations. The first is that we do not report accompanying SV as a comparison. Nevertheless, the goal of this report is not to compare ccFT or LVET to SV but rather to define the physiological boundaries of the ccFT/LVET; previous investigations relating ccFT/LVET to SV against multiple reference standards are enumerated above. Second, we do not have abundant data in the extremes of heart rate, for example during severe bradycardia, cardiac arrest, and severe tachycardia above 200 beats per minute. Thus, we cannot define absolute extremes of pathophysiology, for example, in the moribund or severely unstable patient. Acquiring Doppler data in these patient populations, including cardiac arrest, is on-going. Third, the authors of this manuscript are employees of the start-up building the wearable ultrasound device, while external validation by independent investigators will increase the confidence in our findings, we note that pre-existing data on LVET and ccFT is robust by traditional, hand-held devices, as detailed at the outset.

Conclusion

We report the largest known descriptive analysis of the common carotid corrected flow time as a surrogate for left ventricular ejection time. This was enabled by a wireless, wearable Doppler ultrasound. The average ccFT for all equations studied is the low 300 ms range. With better clinical adoption and deployment of the wearable Doppler, coupled with long-term patient follow up, our dataset will grow. With greater, richer data, we hope to improve Doppler algorithms and predict patient outcomes.

Authors' contributions: LH – conception, figures and tables, analysis and interpretation, drafting
JSK – conception, analysis and interpretation, drafting
CM – analysis and interpretation, critical revisions
IK – analysis and interpretation, critical revisions
SA – analysis and interpretation, critical revisions
AY – analysis and interpretation, critical revisions
JKE – conception, critical revisions
All authors read and approved the final manuscript.

Compliance with Ethical standards and ethical approval: Written and informed consent was obtained for all subjects included in this report, and the study was approved by the local Institutional Ethics Committee.

Consent for publication: Informed written consent was obtained from all the participants of the studies included in the analysis at the time of enrollment.

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