Original Research

Continuous Noninvasive Blood Pressure Monitoring of Beat-By-Beat Blood Pressure and Heart Rate Using Caretaker Compared With Invasive Arterial Catheter in the Intensive Care Unit

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Objective: To examine the accuracy of noninvasively-derived peripheral arterial blood pressure (BP) by the Caretaker device (CT) against invasively measured arterial BP and the fidelity of heart rate variability by CT compared with electrocardiogram (ECG)-derived data.

Design: Prospective cohort study.

Participants: Adult surgical and trauma patients admitted to the intensive care unit.

Setting: Academic tertiary care medical center.

Interventions: In a prospective manner, beat-by-beat BP by CT was recorded simultaneously with invasive arterial BP measured in patients in the intensive care unit. Invasive arterial BPs were compared with those obtained by the CT system. All comparisons among the CT data, arterial catheter data, and ECG data were postprocessed.

Measurements and Main Results: From 37 enrolled patients, 34 were included with satisfactory data that overlapped between arterial catheter and CT. A total of 87,757 comparative data points were obtained for the 40-minute time window comparisons of the 34 patients, spanning approximately 22.5 hours in total. Systolic BP and diastolic BP correlations (Pearson coefficient), as well as the mean difference (standard deviation), were 0.92 and −0.36 (7.57) mmHg and 0.83 and −2.11 (6.00) mmHg, respectively. The overall interbeat correlation was 0.99, with the mean difference between interbeats obtained with the arterial BP and the CT of −0.056 ms (6.0).

Conclusions: This study validated the noninvasive tracking of BP using the CT device, and the pulse decomposition analysis approach is possible within the guidelines of the standard.

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Key Words: blood pressure; heart rate variability; continuous monitoring

CONTINUOUS BLOOD pressure (BP) monitoring is critical in the acute and intensive care settings, and the accurate assessment and tracking of BP are crucial in medical decision-making. However, continuous BP measurement in a beat-by-beat fashion, although desirable, requires invasive arterial catheterization.

Existing continuous noninvasive BP (cNIBP) technologies nearly exclusively are based on the volume-clamp (vascular unloading) technique, or the "Penaz" method. This technique is based on the principle that BP can be estimated by measuring the finger cuff pressure required to maintain constant volume of blood in the finger.[1] Despite the significant efforts to develop more convenient and ubiquitous cNIBP monitors, options for cNIBP monitoring in clinical practice remain limited.[2,3]

The Caretaker (CT) continuous noninvasive physiologic monitor (Caretaker Medical LLC, Charlottesville, VA), which

has been described in detail elsewhere,[4,5] is a recently developed technology that provides beat-by-beat cNIBP, as well as high-resolution interbeat interval information. This device uses a low-pressure (∼35-45 mmHg), pump-inflated finger cuff that pneumatically couples arterial pulsations via a pressure line to a custom-designed piezo-electric pressure sensor for detection and analysis. The CT device is depicted in Figure 1.

The aim of the present study was to assess the accuracy of the CT for two critical physiologic variables, BP and heart rate (HR), against their respective gold standards, arterial catheter-derived BP and electrocardiography (ECG)-based HR, in intensive care unit (ICU) patients.

Patients and Methods

This study was approved by the University of Virginia Medical Center Review Board. The authors recruited patients hospitalized in the University of Virginia surgical/trauma ICU who were monitored using radial intraarterial catheters. Invasive arterial BPs were compared with those obtained by the CT system, which collected pulse-line shapes at the lower phalanx of the thumb of the ipsilateral hand.

BedMaster (Excel Medical, Jupiter, FL) hardware and software were used to digitize and record intra-arterial waveform data and electrocardiography (ECG), with simultaneous time base at a sample rate of 240 Hz (Unity Network, GE Healthcare, Chicago, IL). The catheter/transducer system used consisted of Judkins-type catheters (6-French) and Meritrans pressure transducers (Merit Medical Systems, South Jordan, UT). The frequency response of the system ranges from 0-to-500 Hz, with an accuracy of better than ±1 mmHg. Representative data epochs of 20s were examined using Fourier analysis to determine the relative harmonic amplitude distribution. To ensure the absence of underdamping, which can introduce errors in systolic BP (SBP) exceeding 10 mmHg, the amplitude ratio of the fundamental and sixth harmonic was verified to exceed 1.5 orders of magnitude.[6]

Caretaker Device and PDA Model

The CT is approved by the US Food and Drug Administration and is CE-cleared for the measurement of cNIBP (FDA

K151499), measurement of HR and respiratory rate, and self-calibration (FDA K163255). BP monitoring is accomplished via a pulse-contour analysis algorithm called "pulse decomposition analysis (PDA)", which analyzes the component pulses, specifically the left ventricular ejection pulse (P1) and its reflections, the renal reflection pulse (P2) and the iliac reflection pulse (P3), which constitute the arterial pressure pulse.[7] The model's core BP parameter is the ratio of the amplitude of the renal reflection pulse (P2) to that of the primary systolic pulse (P1), referred to as P2P1. A linear model is used to convert from the P2P1 factor to the SBP and diastolic BP (DBP) components, as follows:

$$P_{systolic} = \alpha_s(AS)\left(\frac{p_2}{p_1}\right) + \beta_s \qquad (1)$$

$$P_{diastolic} = \alpha_d(AS)\left(\frac{p_2}{p_1}\right) + \beta_d \qquad (2)$$

The gain factors of the linear conversion, α_s and α_d, are functions of another PDA parameter, termed AS, that relates to arterial stiffness. The functional form is proprietary. The β_s and β_d parameters are individual patient-specific offsets that are determined during the calibration phase of the CT device. The AS parameter quantifies the spectral content of the arterial pressure pulse. The AS parameter is, in turn, related to arterial stiffness because the mechanical filtering of the arterial wall determines to what extent the structure of the component pulses (P1, P2, and P3) is resolved. Prior work by Callaghan et al demonstrated that this filtering limits the upper observable frequency components in the peripheral arterial pressure pulse to approximately 20 Hz.[8] Preliminary validation tests indicated that the AS parameter tracks expected trends after the introduction of vasoactive agents, as well as age-related population trends. A detailed description of the calculation of the AS factor, as well the motivation therein, is provided elsewhere.[9]

By tracking the pulse waveforms, CT also allows HR measurement via the interbeat interval. HR measurement is another key component of vital sign monitoring in the acute care setting. Moreover, as CT provides interbeat interval information, HR variability (HRV) also can be derived. HRV is useful for assessment of the autonomic system and prediction of cardiovascular risks.[10] Although CT is FDA-approved for a self-calibration procedure that involves an oscillometric sweep of the finger cuff pressure to obtain systolic and diastolic starting pressures for the PDA tracking algorithm, the goal of this study was to isolate and analyze the performance of the tracking accuracy in a postprocess analysis.

Data Inclusion and Exclusion

Radial arterial catheter data were inspected visually, and sections of obvious catheter failure, characterized by either continuous or spurious nonsensical readings, were excluded. Sections contaminated by excessive motion artifact, such that the peak detection algorithm was no longer able to identify heart beats, also were excluded. No separate inspection for the

Fig 1. Depiction of the Caretaker BP device.

ECG data was performed; that is, the same sections of arterial catheter and ECG data were discarded.

In the case of the CT data, a custom signal/noise factor (SNF) was used to identify poor-quality data sections to be excluded. The factor is based on the ratio of the variances of the physiologic signal band to the noise band and obtained using Fourier spectral analysis over an eight-second window with a one-second overlap. The frequency range of the band associated with the physiologic signal was set to 1-to-10 Hz, based on data by the authors and results by others,[8] and the noise band was set to a frequency range of 100-to-250 Hz, which is subject to ambient noise but contains no signal relevant to the base band phenomena of the arterial pressure pulse or its propagation characteristics. Data sections with an SNF <140 were excluded from the analysis. For the 34 patients, the mean percentage of excluded data was 3.4% with a median of excluded data of 1.5%.

Data Alignment and Calibration

All comparisons among the CT data, arterial catheter data, and ECG data were postprocessed. The overlap of the CT data streams and the radial arterial catheter data streams was established after an initial alignment, based on data collection system clocks. This was performed by matching time-based interbeat interval series from the CT data and from the ECG gold standard data, thereby also time-aligning the arterial catheter data that were collected in parallel with the ECG data by the BedMaster system.

For each patient, the first 40-minute overlap section was used for the comparison. Stable overlap sections were defined as having an SNF of at least 140 for the CT data and having stable arterial catheter data, as previously described. In a one-time procedure, a 15-second window at the start of the 40-minute overlap section, was used to calibrate the PDA pulse parameters. Patient-specific PDA constants, once established, were not changed, irrespective of subsequent hemodynamic changes. A 40-minute overlap window was chosen based on BP comparison studies performed by others,[11,12] the motivation being that tracking windows on that time order are reasonable for recalibration, whether internally or externally, in the clinical workflow.

Statistical Analysis

All continuous variables were expressed as mean (standard deviation [SD]). The normality of data distribution was tested with the Kolmogorov-Smirnov test. For both BP and interbeat data series, the authors present graphical correlations and Bland-Altman comparisons including all patients.[13] Mean difference (bias) and 95% limits of agreement representing two SD of the mean difference (precision) were shown in the Bland-Altman plot. Because the large number of data points made it difficult to appreciate the portion of the data point within and beyond the 95% limits of agreement line of the Bland-Altman plot, a histogram of the distribution of the counts is incorporated with each Bland-Altman plot.

Representative correlations and Bland-Altman comparisons are presented for two individual patients. Consistency of the overall BP data was assessed by calculating Cronbach's alpha and the corresponding correlation coefficients for different data ranges. Because the estimation of the difference between the methods was the outcome of interest, no power analyses for sample size estimates were calculated prior to the study. The cohort size was, therefore, driven by patient availability and the American National Standards Institute (ANSI)/Association for the Advancement of Medical Instrumentation (AAMI)/International Organization for Standardization (ISO) 81060-2:2013 standard's required lower limit of 15 patients when an arterial catheter is used for comparison.[14]

Results

A total of 37 patients who were approached were enrolled. Two patients with significant motion artifact resulting in invalid recordings were excluded. One patient, whose CT device accidentally became disconnected early in the session, also was excluded. This resulted in 34 patients with sufficient data that overlapped between arterial catheter and CT. Patient characteristics and admission indications are presented in Table 1. A total of 87,757 comparative data points were obtained for the 40-minute time window comparisons of the 34 patients, spanning approximately 22.5 hours in total. Figures 2 and 3 present overlap examples in the case of a patient with dynamic BP for their interbeat intervals and BP, respectively. Figures 4 and 5 demonstrate the agreement between SBP and DBP, the distribution of counts, and variation in SBP and DBP (eg, patients #17 and #21, respectively). The overall

Table 1
Baseline Patient Characteristics

Characteristic	Mean (SD) or N (%) N = 34	Range
Age, y	44.1 (13.9)	18-64
Male sex	23 (67.6)	
Height, cm	173.3 (9.4)	154.9-189
Weight, kg	95.3 (27.4)	59.3-169.5
Body mass index, kg/m^2	32.0 (8.8)	20.5-55.2
Main Indications for Admission		
Surgery	Procedure type	N
	Liver/kidney transplant	7/1
	Gastric surgery	5
	Thoracic/abdominal/cardiac surgery	5
	Oncology/osteosarcoma	1/1
	Melanoma/facial reconstruction	1
Trauma	Trauma type	N
	Motor vehicle accident	10
	Burn/head injury	1/1
	Necrotizing fasciitis	1
Patient Conditions		
Aortic regurgitation	0	
Nephrectomy	0	
Thoracoabdominal aortic stent or graft	0	

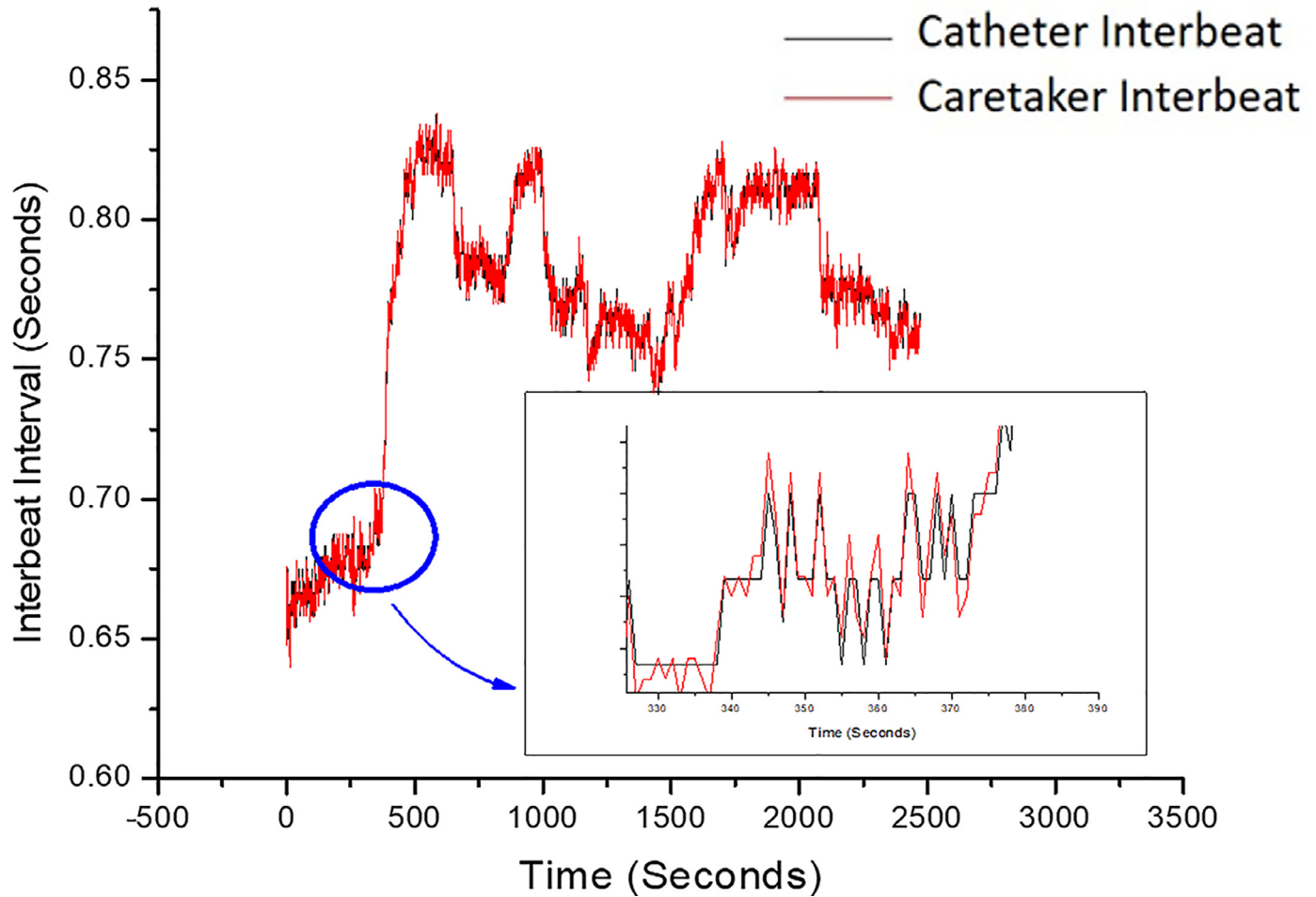Abbreviation: SD, standard deviation.

Fig 2. An example of overlap of electrocardiography-based interbeat intervals obtained from the Caretaker data stream. This presents both an overall overlay of the interbeat intervals, as well as a 70-second expanded section. The correlation (Pearson coefficient) is 0.99 ($p < 0.001$), and the mean difference (SD) is 0.17 (2.75) ms.
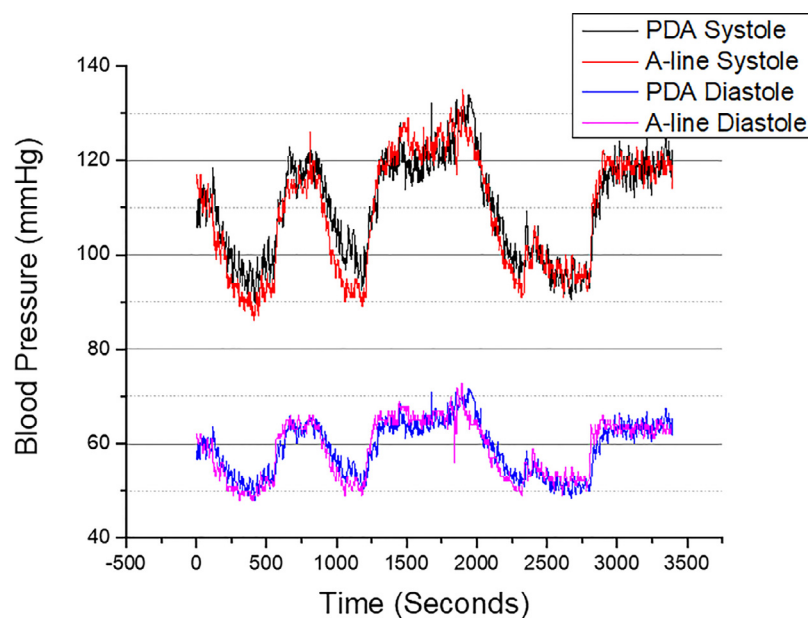

Fig 3. An example of overlap of beat-by-beat systolic and diastolic BPs obtained from arterial catheter (A-line) and Caretaker (PDA) systems. Correlations (Pearson coefficient) and mean difference SD for systole and diastole were, respectively, 0.93 ($p < 0.001$) (4.41) mmHg and 0.91 (3.82) mmHg.
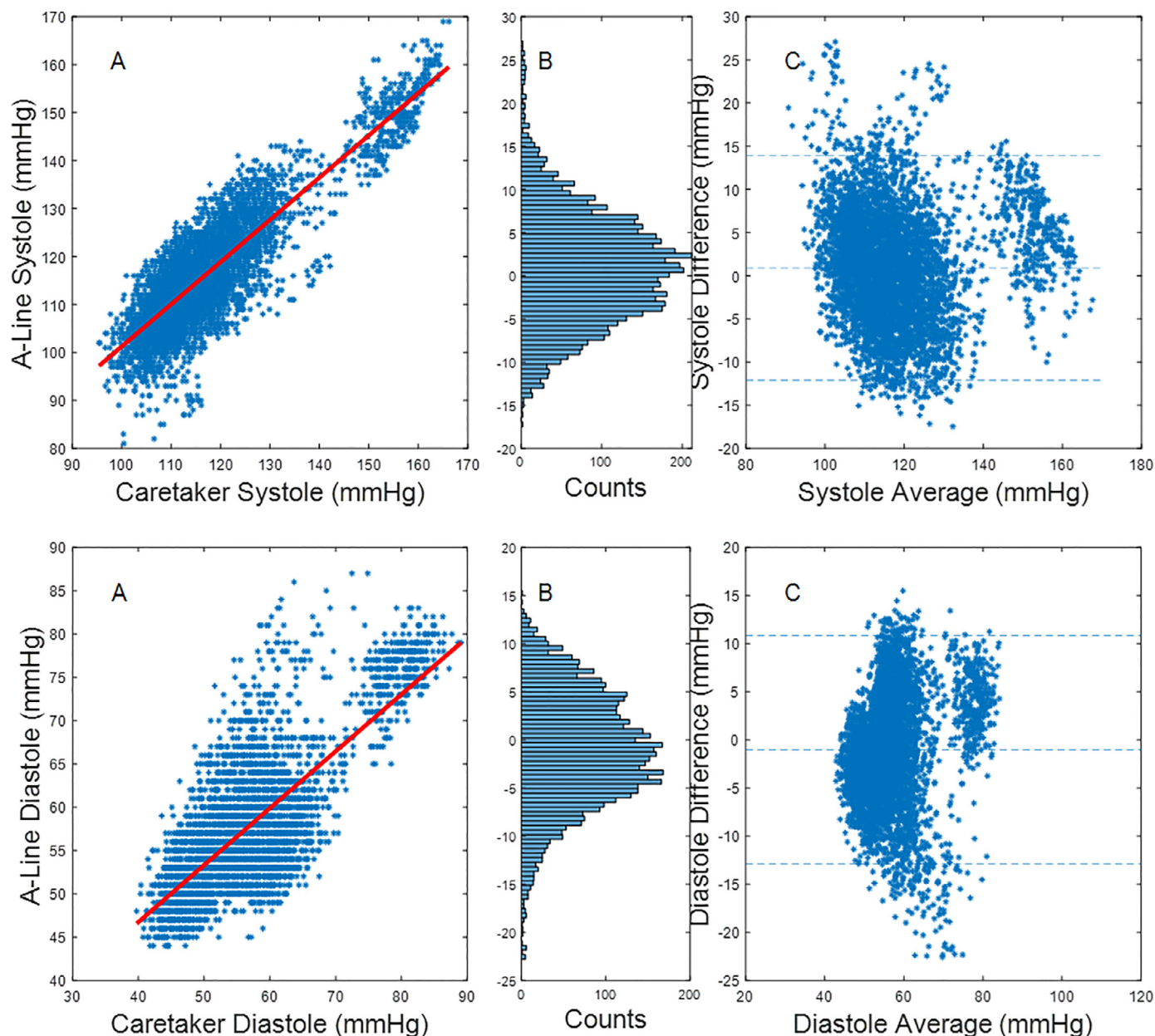
Fig 4. Correlations (panel A), count distributions (panel B), and Bland-Altman results (panel C) for systole (top) and diastole (bottom), for example, patient #17. Results for systole—correlation: 0.83, Bland-Altman results: mean difference 0.89 mmHg (6.48). Results for diastole—correlation: 0.75, mean difference −1.04 mmHg (5.95).

results, for CT measurements of SBP and DBP, respectively, in comparison with invasive BPs for the entire population, are shown in Figure 6. Mean differences (SD) of the two BP measurements for SBP and DBP were −0.36 (7.57) and −2.11 (6.00) mmHg, respectively. The mean difference BP data were normally distributed (Fig 6B, top and bottom). As indicated by Figure 6, there was a wide range of BP manifested from the included patients for SBP and DBP, respectively. Correlations for both SBP and DBP were strong, with an R = 0.92 (p < 0.001; adjusted R^2 0.84) and R = 0.83 (p < 0.001; adjusted R^2 0.69), respectively. Similarly, correlation and agreement were strong for the interbeat interval. The correlation was 0.99 (p < 0.001) (Fig 7A). The interbeat interval data were normally distributed (Fig 7B). The mean difference between interbeats

obtained with the catheter system and the CT was −0.056 (6.0) ms (Fig 7C).

In Table 2, the internal consistency results are presented, specifically Cronbach's alpha and the corresponding correlation coefficients for three different data ranges (early, middle, and latter), as well as the corresponding concordances. Overall Cronbach's alpha for SBP, DBP, and mean arterial pressure was 0.96, 0.90, and 0.93, respectively. The correlation was consistent throughout the three time distributions.

Discussion

The principal finding of this study was the level of agreement between the beat-by-beat BP by CT physiologic monitor
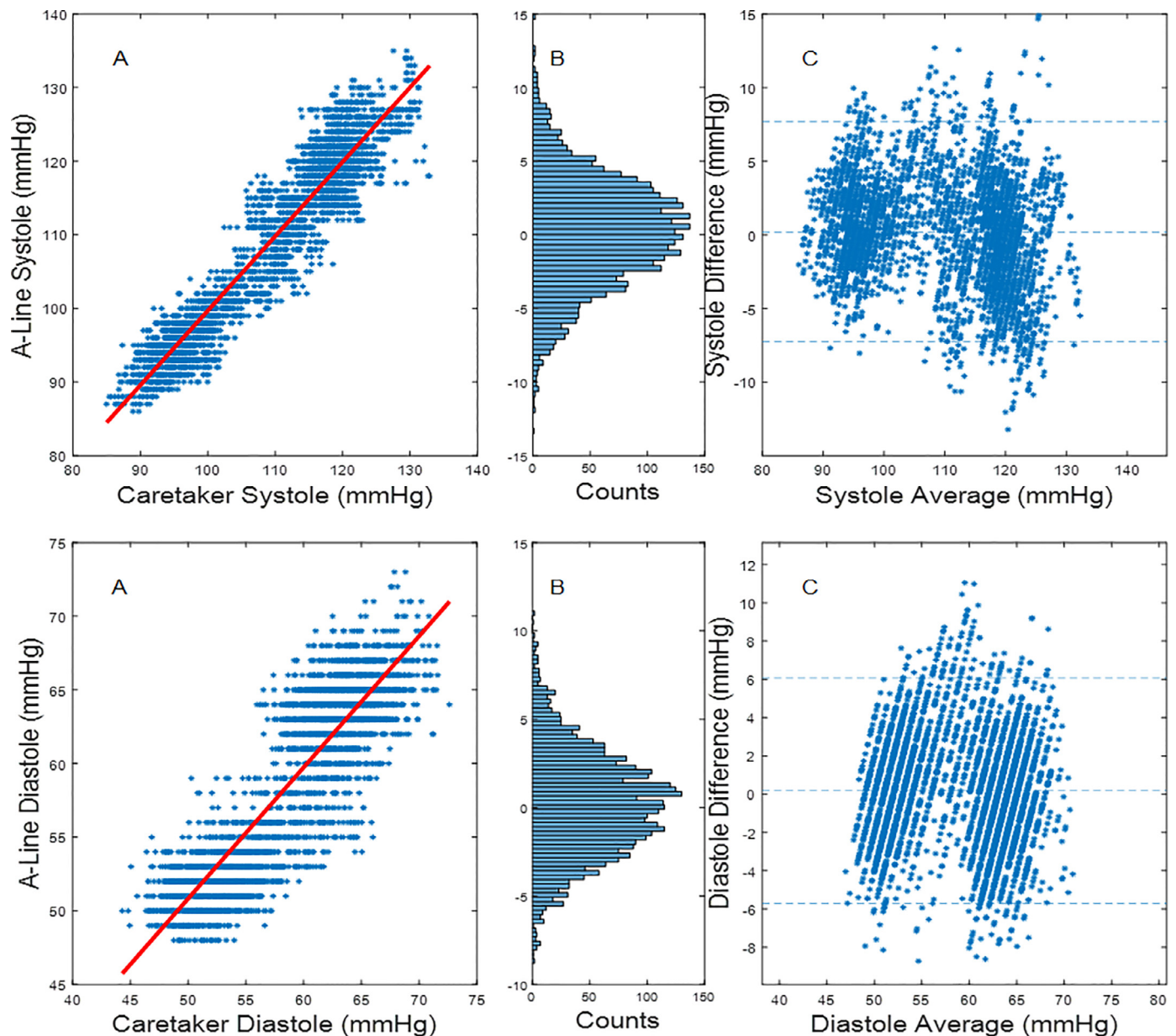
Fig 5. Correlations (panel A), count distributions (panel B), and Bland-Altman results (panel C) for systole (top) and diastole (bottom), for example, patient #21. Results for systole—correlation: 0.89, Bland-Altman results: mean difference 0.69 mmHg (4.3). Results for diastole—correlation: 0.86, mean difference 0.54 mmHg (3.1).

and the gold standard of invasively-measured arterial BP in critically ill patients in the ICU was well within the ANSI/AAMI/ISO 81060-2:2013 standard guidelines.[14] Further, the interbeat intervals were sufficient for higher-resolution HRV tracking than is available with non-ECG systems. Comparison values were obtained for considerable BP ranges in an ICU patient cohort with a broad range of medical issues, physiologies, and ages, supporting the feasibility of this noninvasive and minimally intrusive approach to hemodynamic monitoring.

The purpose of the study was to validate the PDA-based new technology in its continuous beat-by-beat BP measurement directly against the invasive arterial BP measurement. Although correlations for both SBP and DBP were high, stronger correlation was found with SBP than DBP. Although the Bland-Altman analysis for both SBP and DBP showed comparable agreement, there were a few clusters of measurements in which CT DBP underestimated in high DBP range and overestimated in the low DBP range. This methodology in reporting both correlations and Bland-Altman analysis is in line with prior validation studies of other technologies.[15-17]

A number of studies have concluded that current noninvasive BP monitoring technologies are not accurate enough for clinical use when considering the ANSI/AAMI/ISO 81060-2:2013 standard.[18,19] However, it is important to note that there are different challenges associated with the validation of noninvasive BP monitoring technologies. One is related to the comparison gold standards, which, in many cases, are an
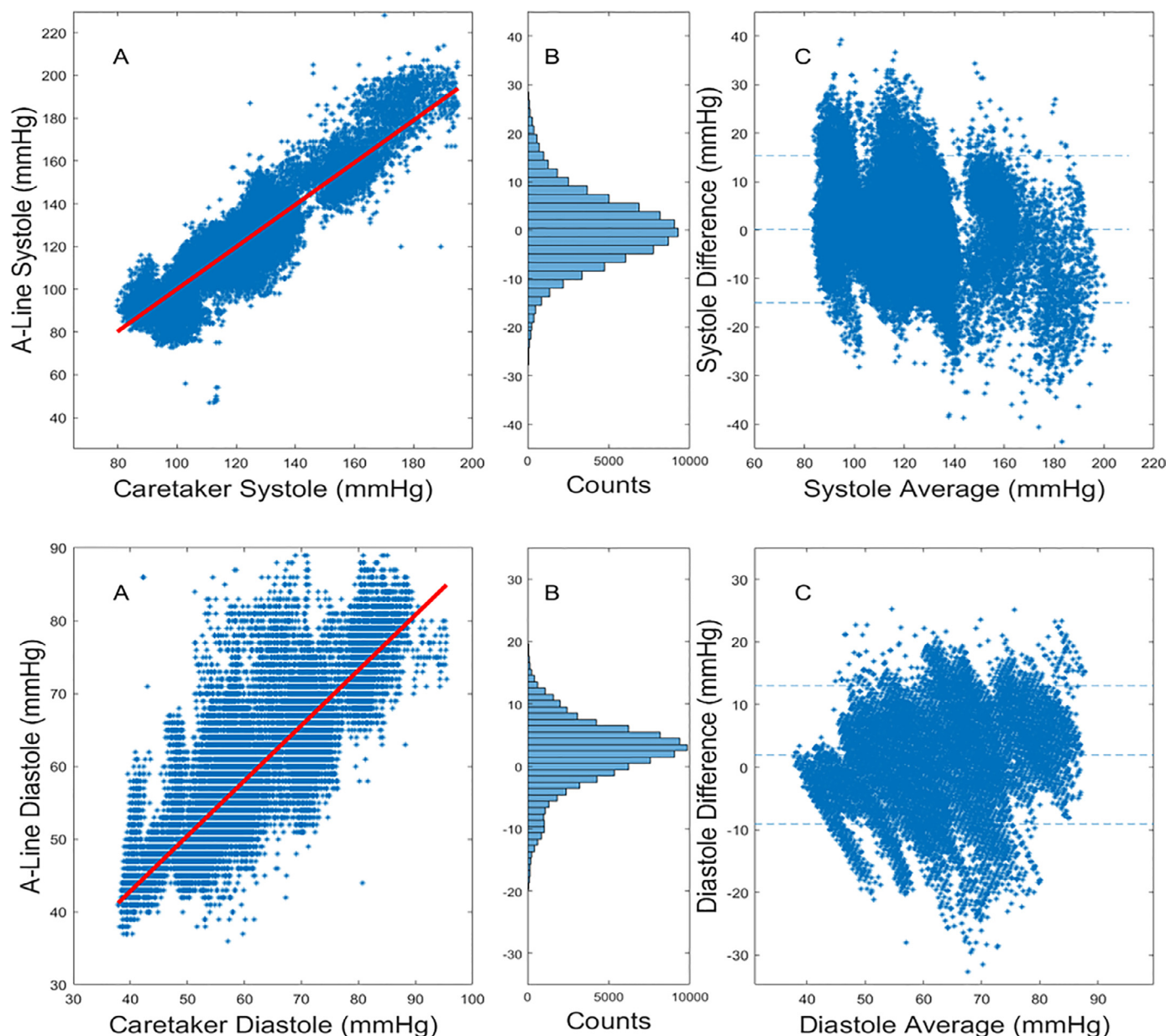
Fig 6. Correlations (panel A), count distributions (panel B), and Bland-Altman results (panel C) for systole (top) and diastole (bottom) for all patients. Results for systole—correlation: 0.92, Bland-Altman results: mean difference 0.36 mmHg (7.57). Results for diastole—correlation: 0.83, mean difference 2.11 mmHg (6.00).

automated cuff. There is no standardization of algorithmic approaches, involving instead different proprietary analyses of the oscillometric amplitude envelope.[20]

Equally important, the challenge in validation also is related to the broad range of variances in human physiology, rather than to just technologic shortcomings. In the comparison of BP obtained from different physiologic monitoring sites, the lack of generally applicable defined functional forms relating them has been well-documented.[21-23] Indeed, a recent study revealed the lack of a consistent general relationship even between SBP measured invasively at the brachial and radial arteries in a cohort of 180 patients.[21] In this study, although 43% of patients presented with differences of <5 mmHg between the two measurement sites, the remainder presented with larger differences. There was a wide range in the

magnitude of difference in radially obtained SBP. There may, therefore, be a limit to which noninvasive BP monitors can match the results obtained invasively, particularly across large patient groups with commensurately varied physiologies and pathologies.

The agreement of CT bias (95% limits) of −0.36 (7.57) and −2.11 (6.00) mmHg for SBP and DBP, respectively, exceeded those of other commercially available cNIBP technologies.[18] Studies using finger cuff devices, such as Nexfin/Clearsight (Edwards Lifesciences, Irvine, CA), CNAP (CNSystems, Graz, Austria), and Finapres Nova (FMS, Enschede, Netherlands), are all based on the volume-clamping method (Penaz principle), and yielded mixed results in both medical and surgical ICUs.[24-28] A meta-analysis by Kim et al reported pooled bias (95% limits of bias) of CNAP against the standard BP that
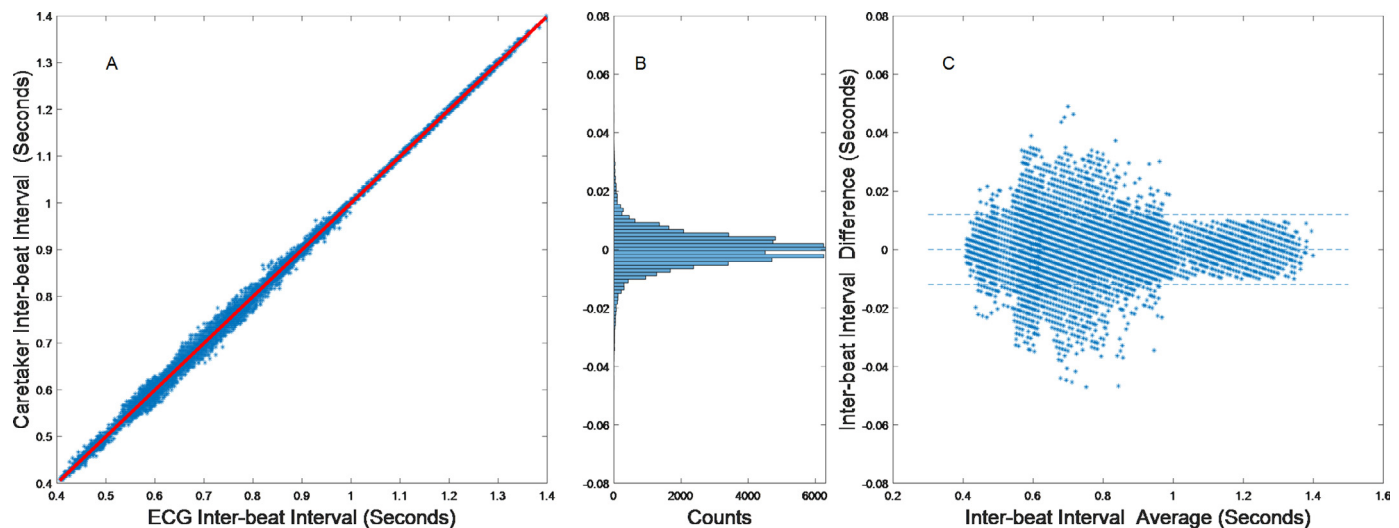
Fig 7. Caretaker overall interbeat interval data correlations (panel A), count distributions (panel B), and Bland-Altman results (panel C). Correlation was 0.999 and adjusted R^2 was 0.999. Bland-Altman results: mean difference −0.056 ms (6.00).

was invasively measured to be −1.8 ± 12.8 mmHg (−26.8 to 23.2 mmHg) and 7.2 ± 8.5 mmHg (−9.5 to 24.0 mmHg) for SBP and DBP, respectively.[18] The pooled bias (95% limits of bias) of Nexfin against the invasively measured standard BP was −1.6 ± 8.4 mmHg (−18.1 to 15.0 mmHg) and 5.1 ± 6.6 mmHg (−7.8 to 18.0 mmHg) for SBP and DBP, respectively. The improved accuracy may be explained in the context of mechanical coupling. Importantly, although the Penaz principle uses an active monitoring modality, CT uses a passive one, performing the mechanical coupling to the arterial wall. A study by others showed more accurate pulse transit time measured by the CT when compared with a Finapres, in recording sessions before and after exercise.[29]

Studies testing another method using arterial tonometry, such as the T-Line System (Tensys Medical, San Diego, CA), also have yielded mixed results.[30-32] The same meta-analysis reported pooled bias (95% limits of bias) of the T-Line System against the standard BP to be −0.1 ± 8.4 mmHg (−16.5 to 16.3 mmHg) and 2.9 ± 6.7 mmHg (−10.2 to 16.0 mmHg) for SBP and DBP, respectively.[18] Although the precision appeared comparable to that of CT shown in the authors' study, 95% limits were much wider. Of note, this device is no longer commercially available.

Much work currently is under way to develop novel cNIBP devices that use indirect and surrogate measures to track BP, such as pulse transit time or pulse analysis using photoplethysmography (PPG). However, a major limitation is that these measures do not depend solely on changes in BP.[4,33,34] Instead, the surrogate measures are subject to other hemodynamically relevant parameters, such as HR or arterial stiffness, which can mask BP-related effects. The PDA model proposes a physiologically based explanation of the structure of the arterial pulse that models and uncovers the interplay of these masking effects. This is different from approaches that seek to correlate features on the pulse alone. Pulse features alone cannot be counted on to persist permanently across the continuum of inter- and intrapatient physiologic states. In other words, there is a great variability in the structure and form of the pulse envelope among patients and even within the same patient. The PDA model seeks to correct for these physiologic changes to give a more precise output.

With regard to HR measurement, CT yielded an accurate interbeat interval when compared with ECG. Specifically, the CT tracked interbeat intervals within a mean difference of <1 ms (6.0 ms) in a range of interbeats from 0.4-to-1.4 seconds, corresponding with HR from 43-to-150 bpm, in a physiologically challenged population across a wide range of ages. Although ECG-derived HR is considered the most reliable and accurate, electrocardiac pathologies, such as atrial fibrillation, can introduce significant HR uncertainties compared with a monitoring methodology that measures the actually ejected pressure/flow pulse, be it mechanically such as the CT that

Table 2

Cronbach's Alpha (Correlation Coefficients [R]) for Systolic BP, Diastolic BP, and Mean Arterial Pressures Divided Into Three Time Periods

	Overall Cronbach's Alpha	1st Third Cronbach's Alpha (R)	2nd Third Cronbach's Alpha (R)	3rd Third Cronbach's Alpha (R)
Systolic BP (overall)	0.96	0.98 (0.96)	0.97 (0.94)	0.88 (0.79)
Diastolic BP (overall)	0.90	0.84 (0.78)	0.96 (0.94)	0.92 (0.84)
Mean arterial pressure (overall)	0.93	0.90 (0.82)	0.97 (0.95)	0.84 (0.74)

Abbreviation: BP, blood pressure.

couples to the arterial pulsation or devices that rely on PPG. Aside from certain arrhythmias, there are issues of resolution and comfort. Although ECG-based HR excels at the former, longer-term wear of the electrodes can lead to skin breakdown and irritation. PPG devices, on the other hand, generally are comfortable, but provide lower resolution, as several studies have demonstrated.[35-37] The interbeat comparison results presented here suggest that mechanically coupling to the arterial pulse can provide a beneficial compromise, providing less-intrusive monitoring, if implemented using a low-pressure finger cuff, while also providing improved resolution.

Limitations of the study included motion artifact issues that necessitated the exclusion of two patients. These artifacts principally were associated with the accommodations necessary to perform research within the clinical workflow of the ICU. Although the vasopressor status is unknown for each patient, no vasopressor or intravenous antihypertensive medication was administered during the recording period of the CT device. Further, no adjustments in vasoactive medications that may have been infusing were recorded for any patient. No patient had significant pathology of the central arterial system, such as an aneurysm, that would influence results, but prospective screening was not performed. Effects due to possible other abnormal central arterial anatomy are unknown.

The technology's relevance in those settings will increase further with additional hemodynamic parameters, such as stroke volume, cardiac output, and left ventricular ejection time, which can be readily modeled within the PDA formalism. Further, the effect of aberrant anatomy, such as abdominal aortic aneurysms or renal artery stenosis, could be investigated in relation to CT BP readings. Validity of the CT in the setting of more extreme BP range and during the titration of vasoactive medications would warrant further investigation.

In conclusion, the authors have presented evidence that the noninvasive tracking of BP and HRV using the CT device and the PDA approach is possible within the guidelines of the ANSI/AAMI/ISO 81060-2:2013 standard. The accuracy exceeded that of existing cNIBP technologies. Based on the results presented, coupled with the convenience of use, the CT has the potential to extend cNIBP monitoring to a wider patient population. Future studies would benefit from involving a more heterogeneous patient population in various clinical settings.

Conflict of Interest

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