ARTICLE

Performance of a cuffless photoplethysmography-based device for continuous monitoring of blood pressure after cardiac surgery: a preliminary validation study

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Accurate and convenient monitoring of blood pressure (BP) is challenging and relies on cuff-based devices or in the postoperative/intensive care settings, on invasive measurements. The aim of this study was to prospectively evaluate the accuracy of BP measurements obtained from a novel, commercially available cuffless, non-invasive photoplethysmography (PPG)-based chest patch monitor in patients after cardiac surgery. This single center prospective preliminary validation study enrolled adults who underwent cardiac surgery. Data generated by the PPG-based device was compared to those of a standard invasive arterial pressure (IAP). Bland-Altman plots and Pearson's correlations were used to assess the accuracy of the PPG-based device. Stability and BP changes were not formally evaluated. Ninety-six patients consented for the study. Mean age was 63.2 ± 12.2 years (range 24–84), and 32 (33%) were women. Average monitoring was 25.6 ± 17.2 h. In total, we evaluated 78,659 readings for systolic BP (SBP), 78,818 for diastolic BP (DBP), and 92,544 for heart rate (HR). The correlation coefficients were r = 0.959, 0.973, 0.966, and 0.962 for SBP, DBP, mean arterial pressure (MAP), and (HR), respectively. The bias ± SD was 0.1 ± 4.8 mmHg for SBP; 0.4 ± 2.1 mmHg for DBP; 0.26 ± 2.6 mmHg for MAP, and 0.15 ± 3.6 beats per minutes for HR. 95% of SBP, and 99.9% of DBP measurements were within 10 mmHg of the reference measurement. In conclusion, the tested cuffless device offers acceptable accuracy and is a promising novel noninvasive tool for continuous BP monitoring. Further studies are needed to validate these findings according to the most updated validation protocols for pulseless devices.

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BACKGROUND

Blood pressure (BP) is a key physiological biomarker, and its measurement is one of the most performed medical procedures in the healthcare setting. Both hypertension and hypotension are associated with high morbidity and mortality. Hypertension, for example, is the leading modifiable risk factor for cardiovascular events [1]. Given the value of this parameter, over several decades, various techniques and devices have been introduced into clinical practice for measuring BP [2]. Recently, novel cuffless devices have been developed to noninvasively measure BP. Their clear advantage is their ability to provide frequent intermittent or continuous (an output period of more or under every 30 s, respectively) measurements in a non-invasive, convenient, and comfortable manner (with no need for arterial occlusion) [3, 4] which may facilitate BP monitoring in the inpatient and outpatient settings. Most are based on Photoplethysmography (PPG) technology, and several have been commercially cleared in the United States or Europe (e.g. Biobeat [5], LiveMetric [6], Aktiia [7]). However, these devices are not endorsed yet by the scientific community and are not included in the American or European guidelines as acceptable alternatives for current devices used in clinical care because their validation standards should be different and are still evolving.

Many cuffless-based devices have been evaluated in various clinical settings. For example, the Biobeat system (WP613, Biobeat Technology LTD, Petch Tikva, Israel) has been previously tested in the outpatient setting and found to provide comparable measurements to those obtained by a standard 24 h ambulatory blood pressure monitor (ABPM) [8]. In a preliminary study of BP monitoring after cardiac surgery, the device showed high level of accuracy compared to invasive intra-arterial pressure (IAP), however, this study included only 10 participants [9].

The aim of this study was to assess the accuracy of a novel cuffless device (Biobeat) for continuous BP monitoring after cardiac surgery against a reference standard, as an important step towards its clinical application, according to the most available requirements known at study design in 2019. Specifically, the current study was

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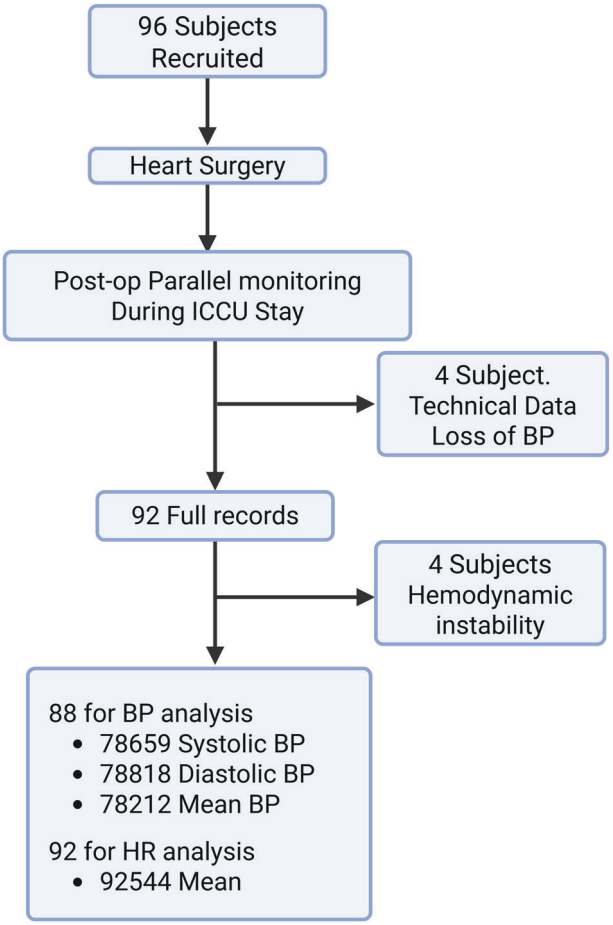

Fig. 1 Experimental design. Blood pressure (BP); Intensive Cardiac Care Unit (ICCU); and Heart rate (HR).

Table 1. Patient characteristics and blood tests at baseline.

Patient Characteristics	**(N = 96)**
Age [years; Mean ± SD]	63.2 ± 12.2
Range [Min, Max]	[24.0, 84.0]
Females	32 (33%)
Height [m; Mean ± SD]	1.69 ± 0.09
Weight [kg; Mean ± SD]	78.3 ± 15.4
BMI [kg/m^2; Mean ± SD]	27.4 ± 4.89
Current Smokers	19 (19.8%)
Obesity	34 (35.4%)
Diabetes mellitus	31 (32.3%)
Congestive heart disease	11 (11.5%)
Hypertension	60 (62.5%)
Ischemic heart disease	40 (41.7%)
Valvular disease	49 (51.0%)
Monitoring duration [hours; Mean ± SD]	25.6 ± 17.2
Median hours [Min, Max]	22.0 [8, 142]
Blood tests at baseline [Mean ± SD]	
Lactate [mg/dL]	16.7 ± 10.0
Base Excess [mEq/L]	−3.05 ± 3.02
HCO_3 [mEq/L]	22.1 ± 2.7
pO_2 [mmHg]	151 ± 64
pCO_2 [mmHg]	40.3 ± 7.9
pH	7.36 ± 0.06
Glucose [mg/dL]	150 ± 38.5
Creatinine [mg/dL]	1.22 ± 1.32
Platelets [1000/μL]	180 ± 57.5
Hemoglobin [g/dL]	11.5 ± 1.7
White blood cells [10^3/mm^3]	15.4 ± 5.8

SD Standard deviation and *BMI* Body mass index.

designed to evaluate the accuracy and the level of agreement between the BP measurements obtained by the cuffless PPG-based device and an IAP monitoring system, in patients in the Intensive Cardiac Care Unit (ICCU) after cardiac surgery.

METHODS

This single center, prospective study recruited males and females 18-years or older admitted to the ICCU after cardiac surgery (Coronary Artery Bypass Grafting or valve surgery) between June 2020 until January 2023 at Chaim Sheba Medical Center, Ramat Gan, Israel, and had a concomitant intra-arterial (radial artery) catheter placed for post-operative BP monitoring per standard clinical care. Exclusion criteria were patients with severe postoperative shock state during the ICCU stay, pregnant women, patients with a lack of judgment/mental illness, and hospital personnel. The study protocol was approved by the institutional review board and registered in ClinicalTrials.gov ID NCT04071015.

Patients gave written informed consent preoperatively, and demographics and other relevant characteristics were collected. In addition, patients' skin tone based on Fitzpatrick scale [10] was recorded per FDA guidelines [11] because skin tone may affect the accuracy of PPG-based devices. The study did not interfere with the operative flow. Post-operatively, patients were monitored in the ICCU as per routine clinically indicated by the institute utilizing the standard IAP system (IntelliVue MX500 Patient Monitor, Philips Medical Systems). "Zeroing" of the IAP system was performed at the beginning of the monitoring [12], and at least once every 8 h and as needed by the bedside nurse, regardless of this study. Biobeat (WP613 device from Biobeat Technology LTD, Petch Tikva, Israel) was attached to the chest wall and initialized according to the manufacturer's instructions (described below) at the start of the monitoring and not repeated at any time for the remaining of the study duration (maximum 5 days). Continuous real-time readings of BP and heart rate (HR) were recorded simultaneously by both Biobeat and a standard IAP monitoring system. The Biobeat monitoring continued as long as IAP was clinically indicated, and up to five days (144 h). Mean arterial pressure (MAP) was calculated from SBP and diastolic BP (DBP). Biobeat can produce one lead ECG tracing, but HR for analysis was intentionally obtained from the cuffless device as generated from the cuffless PPG-based system. All data were processed and analyzed post hoc. Information from the Biobeat device was not available to medical personnel at the time of the study and thus not used in clinical decision-making. Simultaneous measurements of Biobeat and IAP were used for comparison. Valid ranges for HR were considered 35–155 beats per minute (bpm), for SBP 60–300 mmHg, and for DBP 30–150 mmHg due to the IAP calibration ranges and limitations.

Tested device

The WP613 device from Biobeat Technology LTD, based in Petch Tikva, Israel, is a PPG-based device designed to be attached to the chest wall. It emits three different wavelengths of light into the skin and uses a sensor to detect the signals' reflection. The device requires 1–3 BP entries from a cuff-based calibration device for initialization with no additional calibration needed. The device has a battery life of 5 days and communicates wirelessly with a cloud-based processing center. Additionally, it can record a single lead surface ECG for further evaluation. By utilizing an artificial intelligence algorithm in the cloud, the device is FDA-cleared for measuring systolic, diastolic, and mean blood pressure [5]. It can also monitor various other parameters, including heart rate, body temperature, O_2 saturation, cardiac output, stroke volume, systemic vascular resistance, and respiratory rate [13–17].

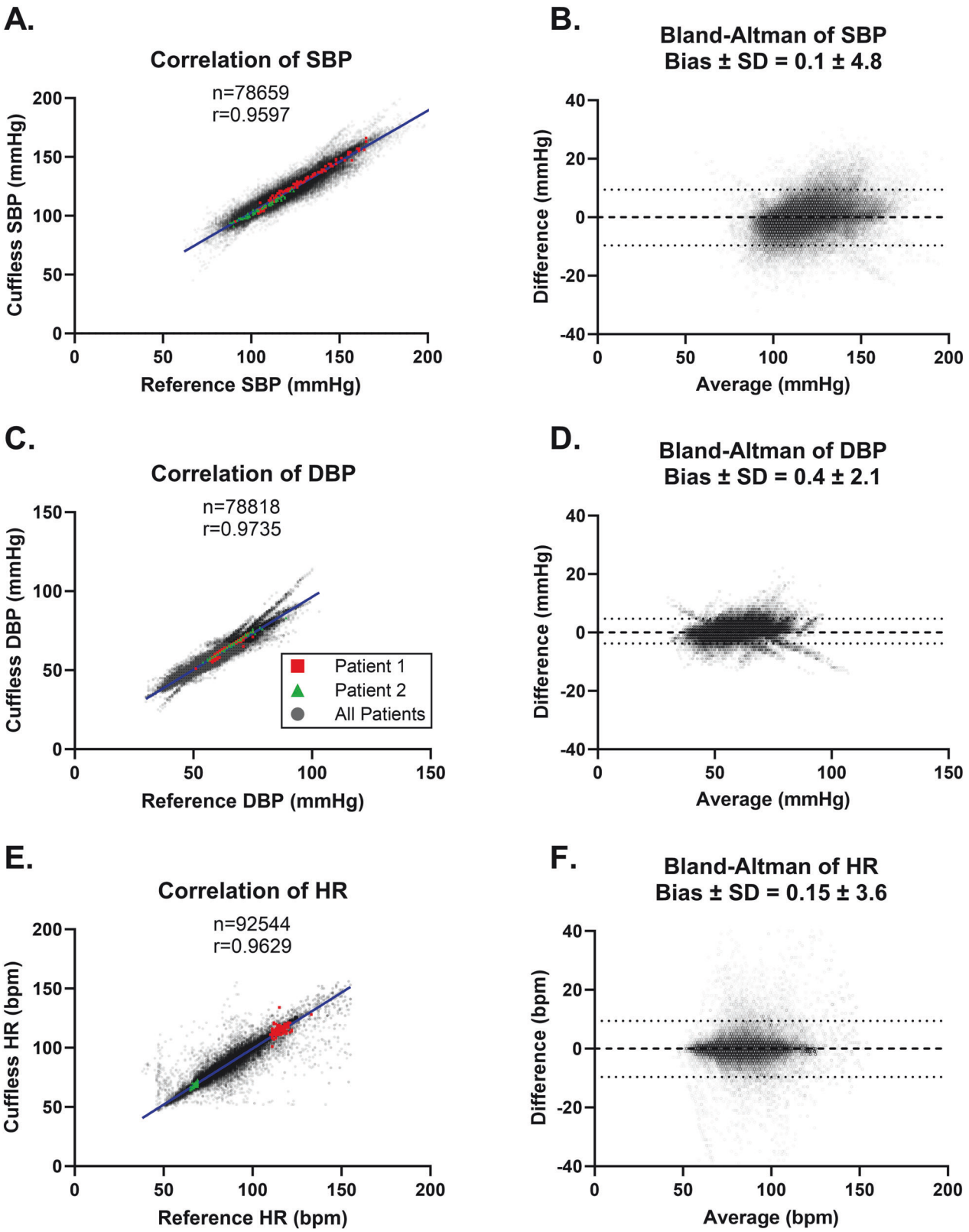

Fig. 2 Correlation and bias of all collected blood pressure and heart rate data. A Correlation of systolic BP between the tested device and IAP measurements, **B** Bland-Altman scatterplot displaying the tested device and IAP systolic BP differencevs their average; **C** & **D** for diastolic BP; **E** & **F** for heart rate. The red and green datapoints are illustrative only and derived from two randomly selected patients. SBP systolic blood pressure, DBP diastolic blood pressure, MAP mean arterial pressure, HR heart rate, SD standard deviation.

Table 2. Bias and correlation of data obtained by the Biobeat device compared to IAP.

	Bland-Altman Bias ± SD	Pearson r	Number of paired measurements	Difference ≤ 5	Difference ≤ 10	Difference ≤ 15
SBP, mmHg	0.1 ± 4.8	0.960	78,659	80%	95%	99%
DBP, mmHg	0.4 ± 2.1	0.974	78,818	97%	99.9%	99.9%
MAP, mmHg	0.26 ± 2.6	0.967	78,212	94%	99.6%	99.9%
HR, bpm	0.15 ± 3.6	0.963	92,544	95%	98%	99%

SBP systolic blood pressure, *DBP* diastolic blood pressure, *MAP* mean arterial pressure, *HR* heart rate, *SD* standard deviation, *bpm* beats per minute.

Table 3. Correlation and bias of the systolic blood pressure estimated by the Biobeat device according to subjects' skin tone based on the Fitzpatrick scale (1–6).

Skin tone (Fitzpatrick scale)	Number (%) N = 96	Number of pairs	Pearson r	p-value	Bias ± SD	95% Limits of Agreement
I	17 (17.7%)	15,718	0.970	<0.0001	0.04 ± 4.56	−8.891 to +8.963
II	16 (16.7%)	11,282	0.950	<0.0001	−0.16 ± 4.48	−8.933 to +8.621
III	22 (22.9%)	14,861	0.958	<0.0001	−0.09 ± 5.24	−10.36 to +10.17
IV	15 (15.6%)	12,533	0.952	<0.0001	−0.07 ± 4.79	−9.454 to +9.317
V	14 (14.6%)	13,335	0.953	<0.0001	−0.01 ± 4.92	−9.656 to +9.634
VI	10 (10.4%)	8007	0.958	<0.0001	−0.04 ± 5.24	−10.31 to +10.24
NA	2 (2.1%)					

SD standard deviation, *NA* not available.

Data Analysis

Bland-Altman plots and Pearson's correlations were used to assess the accuracy and degree of agreement between measurement techniques for each index (SBP, DBP, MAP, and HR). Significant differences were compared using a mixed-effects repeated measures ANOVA approach and deemed statistically significant where $p < 0.05$ with differences described as mean ± standard deviation. All measurements for each subject were also averaged and compared for the entire dataset. A heatmap was plotted to show the number of measurements within 4 groups of precision (0–5, 6–10, 11–15, and above 15 mmHg for BP and beats-per-minute for HR.

This study was designed before the publication of the most recent consensus guidelines for validating continuous pulseless BP devices (ISO. 81060-3:2022 Non-invasive sphygmomanometers; Part 3: Clinical investigation of continuous automated measurement type) [18]. Nonetheless, the age, sex, and BP distribution of the study population fits the regulatory standards. The performance assessments recommended by the guidelines include evaluation of the accuracy, stability, and BP changes. This study addresses one (accuracy) of the three requirements. For the accuracy of blood pressure determination, the acceptance criteria are a) absolute mean value of the differences of the paired values ≤ 6 mmHg and b) standard deviation ≤ 10 mmHg.

RESULTS

Ninety-six (96) patients were recruited in the study. Figure 1 shows the study flow. Among them, 4 patients had no BP log file for IAP due to technical issues, and 4 patients had severe shock state or returned to the operating room with removal of the patch. These patients were excluded due to out-of-range IAP readings (low BP) or ventricular tachycardia or fibrillation, affecting calibration limits. For the BP, 88 patients were included in the final analysis, among whom 80 were treated with inotropic agents during the monitoring period. However, the study did not systematically collect the details of all the medications administered. Table 1 includes the demographics and baseline characteristics of patients. The average age was 63.2 ± 12.2 years (range: 24–84), and 32 (33%) were women. Average monitoring time was 25.6 ± 17.2 h (range: 8–142). In total, 78,659 readings were obtained for SBP, 78,818 readings for DBP, and 78,212 for MAP. For the HR analysis, data from 92 patients were included with a total of 92,544 readings.

Figure 2 and Table 2 show an excellent correlation between all the measurements obtained by the cuffless blood pressure (SBP, DBP, MAP, and HR) and the IAP monitoring system. The correlation coefficients were 0.959, 0.973, and 0.962 for SBP, DBP, and HR, respectively. The Bland-Altman analysis and plot show a bias ± SD of 0.1 ± 4.8 mmHg for SBP, 0.4 ± 2.1 mmHg for DBP, and 0.15 ± 3.6 bpm for HR. The excellent correlation was maintained across the BP continuum with no signs of measurement drift. Further analyses stratified by the different skin tones according to the Fitzpatrick scale (1–6) were consistent with the main results (Table 3).

We conducted further analysis and compared each participant's average BP and HR obtained by the Biobeat and IAP systems. Figure 3 shows significant correlations ($r = 0.99$ for SBP, DBP, and HR) and agreement (bias of 0.3 ± 1.3 and 0.6 ± 0.7 mmHg for SBP and DBP, respectively). Figure 4 illustrates in a heat map the BP and HR bias based on four groups: bias of 0–5, 6–10, 11–15, and >15 mmHg or bpm for BP and HR, respectively. Figure 5 includes representative examples illustrating that the changes in BP and HR measured by IAP were matched by Biobeat. In Fig. 5B, a drift between IAP and Biobeat was due to a delay in the IAP calibration and resolved after calibration. The Supplemental file S1 includes graphs of the BP trend and variation for each patient. The graphs show that changes in BP appear to be well tracked by Biobeat with a small delay and/or changes that are smaller than observed for the IAP for some patients. In addition, the bias, standard deviation, 95% level of agreement and percentages of Biobeat readings within 5, 10, and 15 mmHg of reference (IAP) for each patient are provided (Supplemental file S2). Among the sub-group of patients ($n = 2$) with permanent pacemakers, the correlation was excellent between cuffless BP and the invasive IAP readings with $r = 0.949$ for SBP and 0.974 for DBP (Supplemental file S3). Lastly, we further analyzed the performance of the cuffless device in various patient positions during monitoring. Data was available for nearly half of the measurements. The accuracy was high across

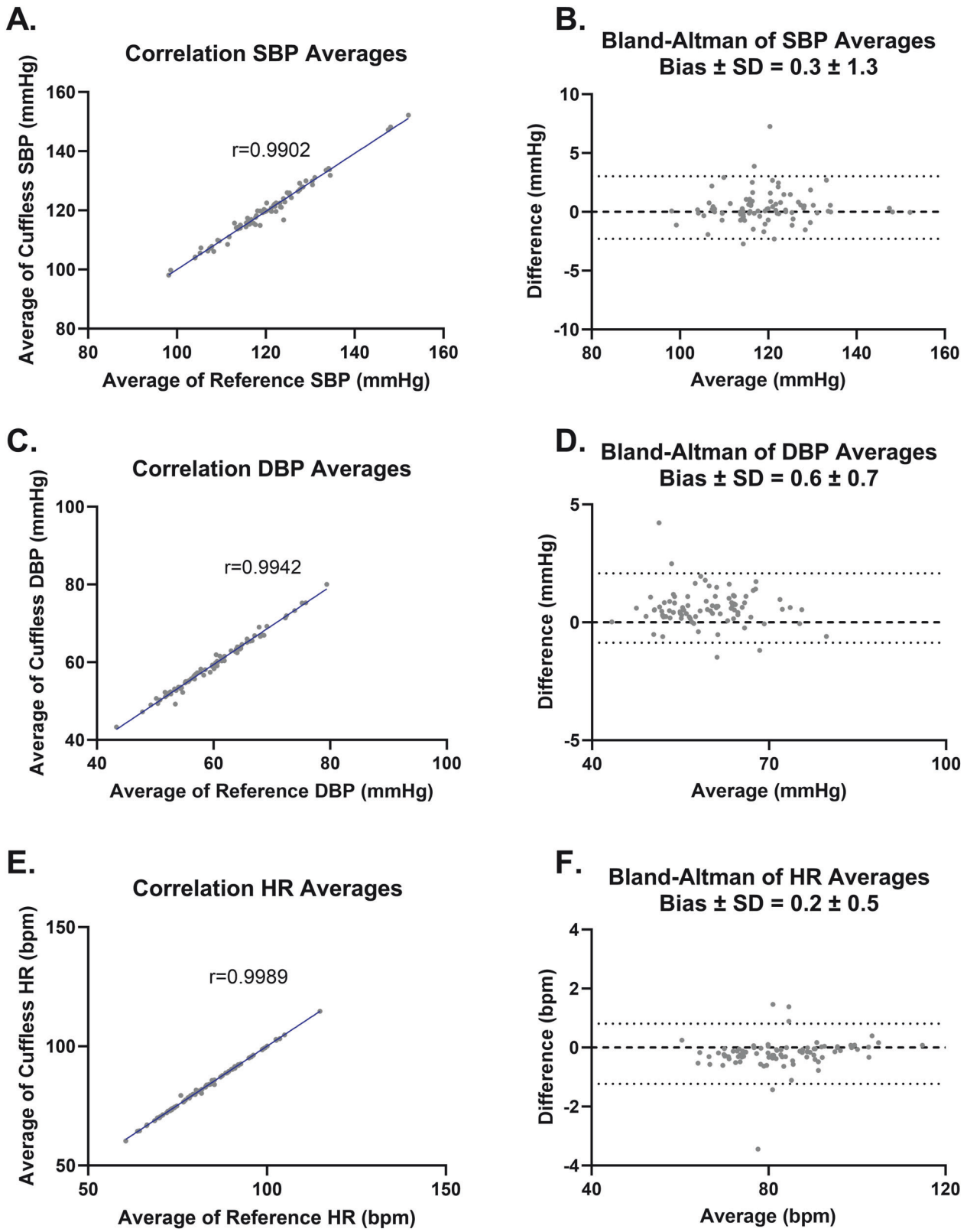

Fig. 3 Correlation and bias of the average blood pressure and heart rate data. A classic presentation of the correlation of the average of systolic BP for each patient, as obtained from tested device and IAP; **B** Bland-Altman scatterplot displaying the tested device patient's average and IAP average for systolic BP difference vs their average; **C** & **D** for diastolic BP, and **E** & **F** for heart rate. SBP systolic blood pressure, DBP diastolic blood pressure, MAP mean arterial pressure, HR heart rate and SD standard deviation.

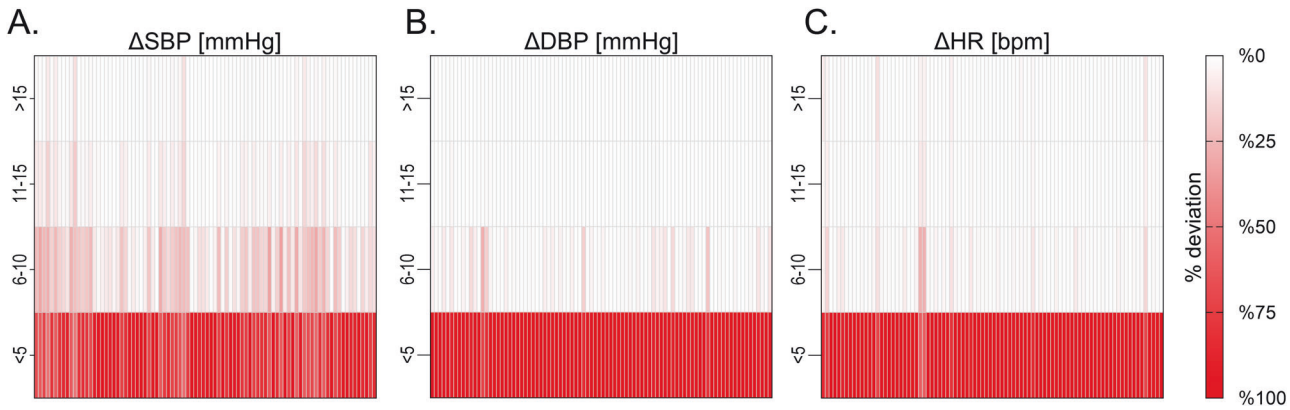

Fig. 4 Distribution of bias within each participant. A represents SBP, **B** DBP, and **C** heart rate. The differences were reported within 4 groups, with differences between 0–5, 6–10, 11–15, and more than 15 units (mmHg for BP and bpm for HR). The darker red color indicates a higher proportion of measurements that fall within that group. 95% of SBP, and 99.9% of DBP, measurements were within 10 mmHg of the reference measurement, and 95.4% of HR were within 10 bpm difference of reference measurement. BP blood pressure, SBP systolic blood pressure, DBP diastolic blood pressure and HR heart rate.

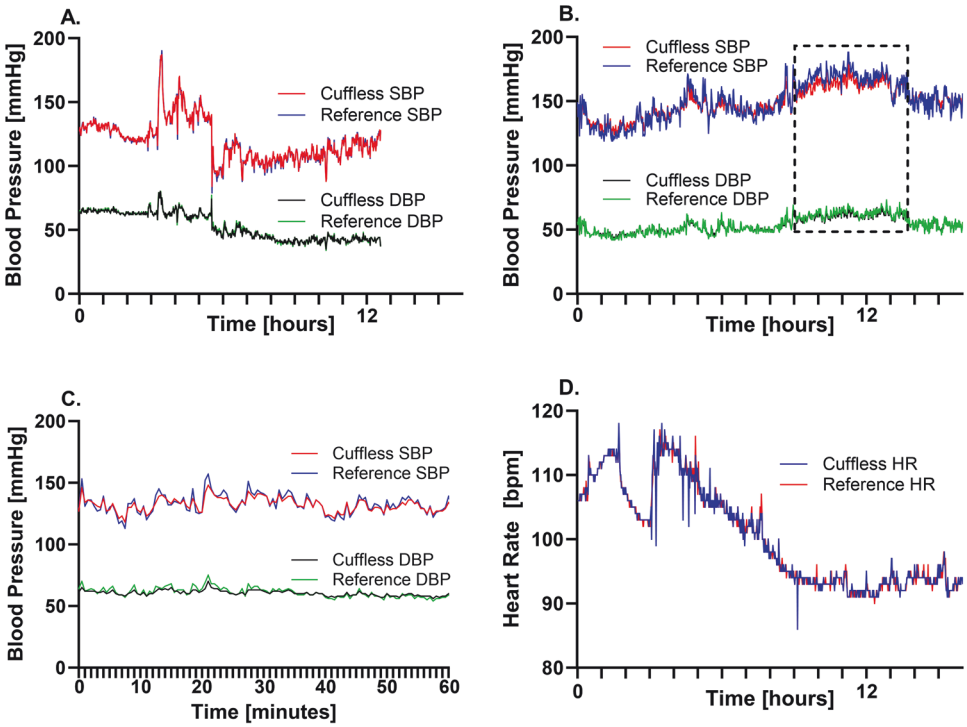

Fig. 5 Representative examples illustrating that the changes in BP and HR measured by IAP were matched by Biobeat over time. A SBP and DBP trends over time during thirteen hours of monitoring. **B** is similar to **A** for another patient; the box shows a drift between IAP and Biobeat due to a delay in the IAP calibration that resolved after calibration. **C** SBP and DBP trend over one hour in a randomly selected patient. **D** HR trend during sixteen hours of monitoring for a randomly selected patient. (Graphs for all patients are included in the supplemental file S1). SBP systolic blood pressure, DBP diastolic blood pressure and HR Heart rate.

different patients' positions as shown in Table 4 for SBP and in the supplementary file for DBP (Supplemental file S4) for DBP.

DISCUSSION

The current study demonstrates excellent correlations, minimal bias, and a high level of agreement in BP and HR measurements between the Biobeat cuffless PPG-based device and IAP. The correlation coefficient was 0.959, 0.973, and 0.962 for SBP, DBP and HR, respectively with a level of agreement and mean error of 0.1 ± 4.8 and 0.4 ± 2.1 mmHg, for SBP and DBP, respectively, and 0.15 ± 3.6 bpm for HR. These results were consistent regardless of skin tone and patients' positions. In addition, Biobeat tracked relatively well changes in IAP BP (Supplemental file S1) although no formal "change test" was planned at study design that preceded the ISO 81060-3: 2022 standard for cuffless continuous devices [18]. These observations suggest that Biobeat may be an alternative for noninvasive and convenient measurements of BP in patients in the ICCU.

The result of this study confirms the findings of a previous small study using the same device [9] and adds to the accumulating evidence in support of cuffless BP devices [19–24]. Most published studies to date have evaluated cuffless devices for "intermittent" ambulatory use (compared with snapshot readings or 24 h ABPM)

Table 4. Correlation and bias of the systolic blood pressure obtained by the Biobeat device according to subjects' position during monitoring.

Position	Number (%)	Pearson r	p-value	Bias ± SD	95% Limits of Agreement
Lying on back	30,981 (37.6%)	0.96	<0.001	−0.17 ± 4.69	−9.37 to +9.03
Lying on left side	2085 (2.5%)	0.98	<0.001	0.39 ± 4.58	−8.6 to +9.37
Lying on right side	3355 (4.1%)	0.96	<0.001	0.62 ± 4.73	−8.66 to +9.89
Sitting in bed	1226 (1.5%)	0.97	<0.001	1.99 ± 5.09	−7.98 to +11.95
Sitting in chair	8854 (10.8%)	0.96	<0.001	0.33 ± 4.85	−9.17 to +9.83
Position unknown	35,808 (43.5%)	0.95	<0.001	−0.17 ± 5.05	−10.06 to +9.73

SD standard deviation, *NA* not available.

rather than "continuous" monitoring after surgery or in the intensive care unit and included a small number of participants. This hinders the ability to validate the results in various populations with different skin tones. The current standards, however, used to validate invasive or cuff-based devices are not appropriate for cuffless devices due to the nature of this novel technology [3]. Because the pace of regulation of these devices did not keep up with the speed of innovation, prior studies have used traditional validation protocols [25]. More recently, consensus on standards by which cuffless BP devices can be tested for accuracy have been developed [18, 26]. Therefore, we expect in the future an acceleration in the adoption of cuffless devices assuming they pass the formal validation process [26, 27]. Since cuffless BP devices estimate BP rather than directly or indirectly measure it, one of the main concerns has been the ability to track BP changes. Our study demonstrated that BP and HR data from Biobeat matched relatively well those from the IAP as illustrated in randomly selected patients **(**Fig. 5**)** and the majority of the enrolled patients (Supplementary file S1); however, this requires further preplanned proper validation based on the ISO 81060-3: 2022 standard for cuffless continuous devices.

BP measurement is critical for clinical decision making both in the acute inpatient setting during hemodynamic monitoring and in the outpatient setting for long term management of hypertension. Yet, the accuracy and ease of obtaining BP measurements is problematic in clinical practice for various reasons (patient, healthcare system, and health care provider or care team factors) that are compounded by time constraints. This can contribute to misdiagnosis or diagnostic uncertainty potentially leading to inappropriate clinical decision making such as under or over treatment or therapeutic inertia. A major advantage of hemodynamic monitoring using PPG technology is its non-invasive nature, wireless set up, ease of operation with minimal training, and the lower risk of complications. While this study evaluated the performance of a cuffless device in the hospital, the technology has a wider application in the outpatient setting. Hypertension is most often diagnosed according to BP levels during office visits (intermittent snapshots) with a cuff-based device, or ideally by ABPM (intermittent recurrent pattern) with a timed cuff-based device. However, ABPM is not widely available and when available, it is not practical or convenient for ongoing monitoring. Thus, home BP measurements using a reliable technique and valid home BP device is now recommended by most major hypertension guidelines [28, 29]. If proven to be accurate, reproducible over time, and able to track BP changes correctly (diurnal variation, antihypertensive drug effects, stress/activity), cuffless BP devices will transform the monitoring and management of hypertension, regardless of skin tone. The ability of this emerging technology to improve clinical outcomes, however, will need to be determined.

LIMITATIONS

Our study has several limitations. First, this is a single-center study that assessed patients during recovery after cardiac surgery, and thus the applicability of the results to other populations and settings needs to be determined. Patients were non-ambulatory (lying in bed or sitting in a chair) during the study, and further studies to evaluate the ability of PPG-based devices to track BP should be performed in other settings. Second, this study was designed before the consensus guidelines for validating pulseless BP devices were published. These guidelines have more stringent requirements, and future studies should be planned and conducted accordingly. Nonetheless, we have presented comprehensive data and analyses as recommended by these guidelines and the results fulfill the accuracy standard. Third, Biobeat can be used as a "continuous" or "intermittent" cuffless device, but each mode requires a different validation process depending on the intended use. In this study, the comparison was done with IAP, which is the gold standard for continuous monitoring, however, this does not apply for intermittent ambulatory use in which the gold standard comparator is a 24 h ABPM or manual auscultatory by trained and certified personnels, using a validated cuff device. Lastly, even the gold standard (IAP system) is not without flaws especially when performed as part of clinical practice rather than a formal investigation. IAP needs frequent calibrations, especially when changing the bed level, raising the head of the bed, and with posture changes, which can affect the reference BP readings and the interpretation of the results.

CONCLUSION

The tested cuffless device (Biobeat) offers a high level of accuracy and agreement for BP and HR compared to data obtained by IAP monitoring in post-cardiac surgery patients with different skin tones and different positions. Further studies are needed to validate these findings in various populations and clinical settings according to the recently adopted validation protocols for cuffless devices.

SUMMARY

What is known about the topic

- Blood pressure (BP) monitoring after surgery is challenging and relies on cuff-based devices or invasive intra-arterial monitoring.
- Photoplethysmography (PPG)-based technology is a promising non-invasive tool to estimate BP in a frequent and convenient manner.
- Data on accuracy of PPG devices for continuous monitoring is limited, in particular among individuals with various skin tones.

What this study adds

- The tested PPG-based device (Biobeat chest patch) in individuals with various skin tones undergoing cardiac surgery

provides accurate and reliable measurements compared to invasive intra-arterial measurements.
- This study supports the use of this novel non-invasive device for continuous BP monitoring, but further studies are needed to confirm these findings according to the evolving and updated validation criteria.

DATA AVAILABILITY

Data underlying the article will be shared at reasonable request to the corresponding author.

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AUTHOR CONTRIBUTIONS

EH and ZZ conceived, designed, wrote, and oversaw all aspects of the study and manuscript preparation. TJ, EZ, and EK were responsible for conducting the study, recruiting participants, and critically reviewing the manuscript. PK and MM performed the statistical analyses and contributed to manuscript review. MDL, LOL, and AL provided critical review and important intellectual input to the manuscript. All authors read and approved the final version of the manuscript.

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COMPETING INTERESTS

Dr Amir Lerman serves as an advisor to Biobeat. All other co-authors declare no competing interests.

ETHICS APPROVAL AND CONSENT TO PARTICIPATE

The study was performed in accordance with the relevant guidelines and regulations. The study protocol was approved by the local institutional review board and registered in ClinicalTrials.gov ID NCT04071015. All participants provided an informed consent to participate in the study. The manuscript does not include identifiable images from human research participants.

ADDITIONAL INFORMATION

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