Continuous Non-invasive Blood Pressure Measurement Using VitalstreamTM is Comparable to Invasive Intraarterial Pressure in Children Undergoing Major Surgery

Karen Boretsky (karen.boretsky@childrens.harvard.edu)
Boston Children's Hospital
Vivian Nasr
Boston Children's Hospital
Douglas Atkinson
Boston Children's Hospital
Martin Baruch
Caretaker Medical

Research Article

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Abstract

Background

Accurate blood pressure monitoring is essential in many clinical scenarios for adults and children. A novel continuous non-invasive arterial pressure monitoring device using a pulse contour algorithm (pulse decomposition analysis), Vitalstream™, was recently cleared by the United States Food and Drug Administration for use in patients 18 years of age and older. Recently published ISO 81060–3:2022 standards for continuous automated blood pressure measurement were used to determine the accuracy (bias) and precision (repeatability) of the device in children ages 2–17 undergoing major surgeries compared to intraarterial blood pressure monitoring. Accuracy and precision are defined as acceptable if bias is within 6 mmHg and standard deviation within 10 mmHg.

Methods

A sample of 31 children ages 2–17 years scheduled for major surgery requiring invasive arterial blood pressure monitoring were consented to participate. Each patient was monitored with a radial arterial catheter and a Vitalstream™ monitor. Hemodynamic measures obtained from both systems during at least thirty minutes of simultaneous monitoring during the surgical procedure were analyzed using Pearson correlation coefficients as well as Bland-Altman and 4Q plot trend analyses.

Results

The correlations of systolic and diastolic arterial pressures were, respectively, 0.77 and 0.68. The Bland-Altman comparisons yielded bias (standard deviation) of 3.79 (9.74) mmHg and − 1.72 (8.45) mmHg for, respectively, systolic, and diastolic arterial pressures, ($p < 0.001$ for all comparisons). Concordances for systole and diastole were, respectively, 0.82 and 0.85.

Conclusions

In this study, continuous, beat by beat blood pressure measured using the non-invasive Vitalstream™ device correlated well with invasive arterial catheter measurements in the children. Most patients exhibited good agreement between methods, and the results were within established ISO limits for the validation of continuous automatic arterial pressure monitoring. The Vitalstream™ may offer low risk, accurate blood pressure monitoring in children ages 2–17.

The trial was registered at clinicaltrials.gov (NCT04817137)

Background

Blood pressure (BP) measurement during surgery is not routinely monitored continuously due to a lack of appropriate non-invasive technology. Intermittent BP monitoring is, however, suboptimal in the operating

room, where rapid changes in BP are common. Invasive arterial pressure monitors are placed in adults and children but are not without risks and limitations.

A NIBP device, Vitalstream™ (CareTaker Medical^{TM},Charlottesville,Virginia), received United States Food and Drug Administration (FDA) clearance for use in adults.[1] The wireless system and technology are described elsewhere.[1] The Vitalstream™ tracks central aortic BP via analysis of the peripheral pulse at a distal site, typically a finger. The device uses a low-pressure (35-45mmHg) pump-inflated cuff surrounding the third digit (Fig. 1) that couples the arterial pulsations to a pressure sensor for digitization and processing. The generated continuous NIBP measurements correlates with systolic and diastolic invasive BP in adults[3] compliant with ANSI/AMI/ISO81060-2:2013 standards.[7] The technology has not been validated in patients under 18 years-old.

We designed a prospective method-comparison study to evaluate the accuracy (bias) and precision of the Vitalstream in determining BP data in children within standard guidelines (ISO81060–3:2022) for continuous automated BP measurement. We hypothesized that the VitalstreamTM's measurements would match measurements from invasive arterial monitoring within limits of the standard.

Methods

The study design is a prospective method-comparison study of patients requiring invasive arterial blood pressure monitoring for major surgery to determine accuracy and precision between systolic and diastolic BP when measured by standard invasive arterial monitoring compared to the Vitalstream™ device. This study was approved by the University's Institutional Review Board (IRB-P00037138) and written informed consent was obtained from all subjects, a legal surrogate, the parents, or legal guardians for minor subjects. The trial was registered prior to patient enrollment at clinicaltrials.gov (NCT04817137), Principal investigator: Karen Boretsky MD, https://clinicaltrials.gov/ct2/show/NCT04817137, First posted date:26/03/2021. For clarification, Vitalstream information was not used to make clinical decisions and did not replace any monitor used for standard care.

Inclusion criteria were patients ages 2–17 years old with planned invasive arterial blood pressure monitoring as part of the anesthesia care plan at the Boston Children's Hospital Longwood campus. Exclusion criteria were patients with vascular or congenital heart disease known to affect large and small arteries, and patient or guardian refusal.

The principal investigator (PI), co-investigators and/or clinical research coordinators associated with the study identified potential patients from pre-operative schedules. Patients and their guardians were approached for consent, and participation was voluntary.

Demographic data collected: Patient age, weight, surgical procedure, co-morbidities, ASA status, and gender.

Non-invasive oscillometric BPs were performed every 5 minutes before general anesthesia induction and arterial line insertion. The attending anesthesiologist inserted an arterial catheter percutaneously and connected it to a disposable pressure transducer with standard low-compliant tubing. The transducer was placed at heart level and zeroed to ambient pressure. The transducer data was automatically digitized, processed, and collected using the Datex-Ohmeda S/5 Collect system (Datex-Ohmeda Division, Instrumentarium Corporation, Helsinki, Finland). The system provides systolic and diastolic blood pressures with 1-minute resolution, averaged over 10s intervals.

The non-invasive Vitalstream™ was placed on the patient's finger as described and the device's self-calibration procedure, which takes about 25 seconds, was initiated. The device scanned the finger cuff's coupling pressure from 0 to 250 mmHg while collecting the pressure-modulated arterial pressure pulse signal. Systolic and diastolic blood pressures were calculated from the processed signal envelope at the end of the pressure scan. After that, the device operated in the continuous tracking mode with the finger cuff pressure collecting pulse data at a fixed baseline cuff pressure between 20 and 45 mmHg. The coupling pressure for continuous operation was determined as part of the self-calibration procedure. A minimum of 30 consecutive, uninterrupted minutes of data was collected and saved in digital format for analysis.

Data inclusion:

The invasive arterial monitoring data was inspected by the PI, and apparent measurement artifacts were excluded. A custom signal/noise factor was similarly used to identify and exclude Vitalstream™ data with poor quality. The factor is based on the standard ratio of the variances of the physiological signal band to the noise band and obtained using Fourier spectral analysis over an 8s window with 1s overlap. The frequency range of the band associated with the physiological signal is set to 1–10 Hz, based on data by the authors and results by others, while the noise band is automatically set to the 100–250 Hz frequency range, 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 below 80 were identified and excluded.

All comparisons between Vitalstream data and arterial catheter data were post-processed. Time stamps in the respective systems were used to align timing. For each arterial catheter data point, with 1-minute resolution, the beat-by-beat Vitalstream readings were averaged over a time window of 20 seconds, bracketing the arterial catheter reading.

Statistical analysis:

Statistical analysis compared the accuracy of the Vitalstream™ systole and diastole values with the corresponding arterial catheter data, as well as the Vitalstream^{TM}'s trending ability for both blood pressure components relative to the reference. The analysis was performed using the MATLAB software package (Natick, USA).

Accuracy (bias) and precision against the reference measurements were assessed via Bland–Altman analyses. In addition, standard concordance analysis of the trend values (with a 15% exclusion zone) was assessed using 4-Quadrant plots in which differences in successive measurements for each device were plotted to compare the agreement in magnitude and direction of values.[7] The Bland–Altman analyses took repeated measurements per subject into account, as required by the standard ISO 81060–3:2022.[8] Cohort size of 31 was driven by the ANSI/AAMI/ ISO 81060- 2:2013 standard's[7] required lower limit of 20 children less than 17 years of age when an invasive arterial line is used for comparison, as well as the 81060-3 requirements that link the number of repeated measurements per patient with the number of required patients based on an estimated intra-class correlation coefficient (Icc) that compares the between-subject and within-subject variances. Assuming conservatively an Icc in the range of 0.6 to 0.7, the corresponding required pair of (repeated measurements per patient/number of patients) is 29/30.[7]

Results

A total of 31 consecutive patients were enrolled from October 2021 through July 2022. No patient who was approached declined participation. Data were excluded for motion artifacts or invalid recordings. Patient characteristics (m/f: 11/20, mean age: 8.16 y (SD: 4.36 y), mean weight: 32.7 kg (18.7) and surgical procedures are presented in Table 1.

Table 1:

Patient Characteristics & Procedure

	Mean
Age	8.16
Weight (kg)	32.73
Gender	11m / 20 f
Procedures	n
Orthopedics, spine	13
Plastics	4
Esophageal Atresia	8
Cardiac	4
Orthopedics, other	1
Mass resection	1

A total of 1460 matched data points were obtained, spanning approximately 24.6 hours of monitoring time.

The statistical comparison for the systolic BP measured by the Vitalstream^{TM} versus arterial catheter is presented as correlation and Bland-Altman analysis. (Fig. 2) Pearson correlation (panel A): 0.77; Count distribution with bin width (Panel B): 2.22 mmHg; Mean difference (bias/accuracy) (Panel C): 3.79 mmHg; standard deviation (precision): 9.74 mmHg. MAE = 20.8 %. LOA: (-22.8, 15.3).

The statistical comparison for the diastolic BP measured by the Vitalstream^{TM} versus arterial catheter is presented as correlation and Bland-Altman analysis. (Fig. 3) Pearson correlation (panel A): 0.68. Panel B: Count distribution with bin width: 0.7 mmHg. Panel C: mean difference (accuracy): -1.72 mmHg, standard deviation (precision): 8.45 mmHg. MAE = 31.2 %. LOA: (-18.3, 14.8).

The trend results, concordances, for systole and diastole were, respectively, 0.82 and 0.85. Fig. 4 and 5

Discussion

This is the first study to validate the accuracy of blood pressure measurements by the Vitalstream device in children using FDA grade standards. The Vitalstream and the invasive arterial devices had comparable systolic, mean, and diastolic pressures during the matched 30-min interval. The results for the 30-minute comparison period were a bias of 3.79 mmHg and a standard deviation of 9.74 mmHg, falling within the specifications of the study design. These specifications were based on the requirement of the AAMI standard that states that bias should not be greater than 6 mmHg and standard deviation should not be greater than 10 mmHg when using the Bland-Altman analysis. Further analysis using 4-Quadrant and polar plots confirms these results and shows minimal bias and adequate concordance. The FDA currently uses this standard for approval of devices.

Since the estimation of the difference between the Vitalstream and arterial line was the outcome of interest, a power analysis for sample size estimates was not calculated prior to the study. The clinically acceptable difference specified in the design phase is used to interpret the findings. The final cohort size of 31 was determined primarily by patient availability and is 1.55 times larger than the required size of 20 patients using the AAMI standard when an invasive arterial line is used for comparison (http://my.aami.org/aamiresources/previewfiles/8106002_1 306_preview.pdf).

When real-time measurement of arterial BP is necessary for the management of major high-risk surgeries, invasive indwelling arterial pressure catheters are placed in children but have complications and drawbacks.[2] Insertion of an arterial cannula can lead to artery injury, requires skill, and consumes costly operating room time. There are situations, especially in small children, where cannulation is extremely difficult or impossible. [2] In uncooperative children, invasive arterial cannulation is performed after anesthetic induction without the benefit of real-time monitoring during the induction. The complications of radial artery cannulation include thrombosis, occlusion of the vessel with limb ischemia, hemorrhage,

and infection. Blood pressure measurements from the Vitalstream™ would be available before anesthetic induction and may circumvent these issues.

There were not any complications reported. Specifically, there were no reports of impaired blood flow to the monitored digit. The Vitalstream system has a low risk of causing digit ischemia because it operates at a coupling pressure significantly lower than normal diastole. Safety, however, cannot be concluded from the study since the sample was small, and no patients were hypothermic or in low perfusion states.

The study has limitations. First, the results cannot be generalized to patients with altered peripheral perfusion since included patients did not have significant cardiovascular disease, were maintained under general anesthesia at normal temperature, and were not treated with vasoconstrictive medications. Furthermore, there was insufficient data to evaluate the device's accuracy when blood pressure was abnormally low or high. Finally, this study did not evaluate the performance of the Vitalstream device in infants and children under the age of 2 years.

In conclusion, the authors have presented evidence that the noninvasive continuous BP using the Vitalstream™ device meets industry standards for accuracy and precision in children ages 2–17, like the published results in adult patients. Based on these results, coupled with the convenience of use, the Vitalstream™ has the potential to extend continuous NIBP monitoring to a wide pediatric population. Future studies would benefit from involving a more heterogeneous patient population in various clinical settings.

Glossary of terms

BP: blood pressure; NIBP: noninvasive blood pressure; FDA: United States Food and Drug Administration; AAMI: Association for the advancement of medical instrumentation; MAP: Mean arterial pressure; PDA: Pulse decomposition analysis; SD: Standard deviation; SNF: Signal/noise factor.

Declarations

Ethics Approval & Consent to Participate: We confirm that this human experiment was performed in accordance with relevant guidelines and regulations (Declaration of Helsinki). This study was approved and overseen by the Boston Children's Hospital Institutional Review Board (IRB-P00037138) and written informed consent was obtained from all subjects, a legal surrogate, the parents, or legal guardians for minor subjects.

Consent for Publication: Not applicable

Availability of Data and Materials: The datasets used and/or analyzed during the current study are available from the corresponding author on reasonable request.

Competing Interest: Karen Boretsky, Vivian Nasr, and Douglas Atkinson no competing interests. Martin Baruch declares his employment with the manufacturer of the Vitalstream device used in this study, Caretaker Medical, Charlottesville, VA.

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Authors' Contributions:

Karen Boretsky MD: Study design; patient enrollment; write and review the manuscript.

Viviane G. Nasr MD, MPH: Patient enrollment; wrote and reviewed the manuscript.

Douglas Atkinson MD: Patient enrollment; wrote and reviewed the manuscript.

Martin Baruch PhD.: Study design; wrote and reviewed the manuscript.

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Conflicts of Interest: Karen Boretsky, Vivian Nasr, and Douglas Atkinson no conflict of interest. Martin Baruch declares his employment with the manufacturer of the Vitalstream device used in this study, Caretaker Medical, Charlottesville, VA.

Clinical trials.gov: NCT04817137

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Figures

Figure 1

The Vitalstream [TM] wearable monitor for the continuous non-invasive BP monitoring

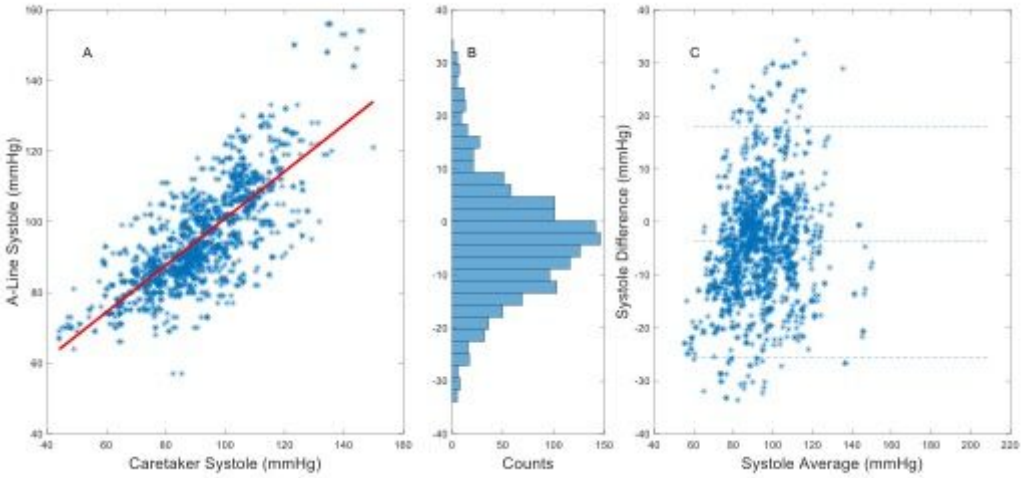

Figure 2

Overall statistical results of Vitalstream / arterial catheter systole comparison: Pearson Correlation (panel A): 0.77. Panel B: Count distribution with bin width: 2.22 mmHg. Panel C: mean difference (accuracy): 3.79 mmHg, standard deviation (precision): 9.74 mmHg. MAE = 20.8 %. LOA: (-22.8, 15.3).

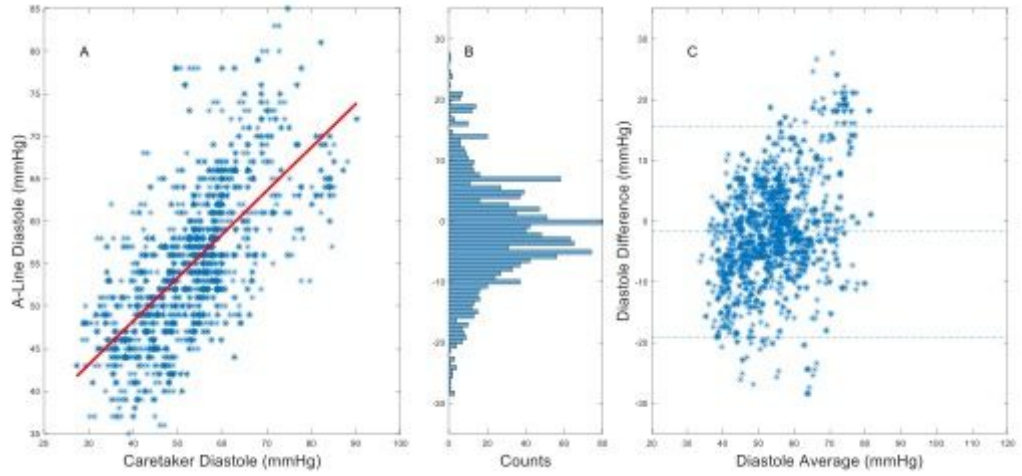

Figure 3

Overall statistical results of Vitalstream / arterial catheter diastole comparison: Pearson Correlation (panel A): 0.68. Panel B: Count distribution with bin width: 0.7 mmHg. Panel C: mean difference (accuracy): -1.72 mmHg, standard deviation (precision): 8.45 mmHg. MAE = 31.2 %. LOA: (-18.3, 14.8).

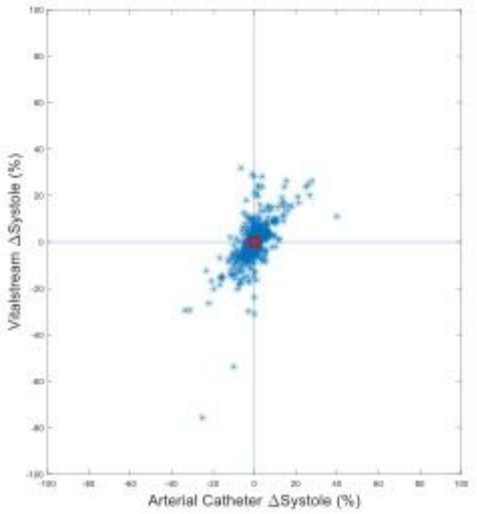

Figure 4

Result of trend analysis for systole comparison. Concordance: 0.82 with 15% exclusion window.

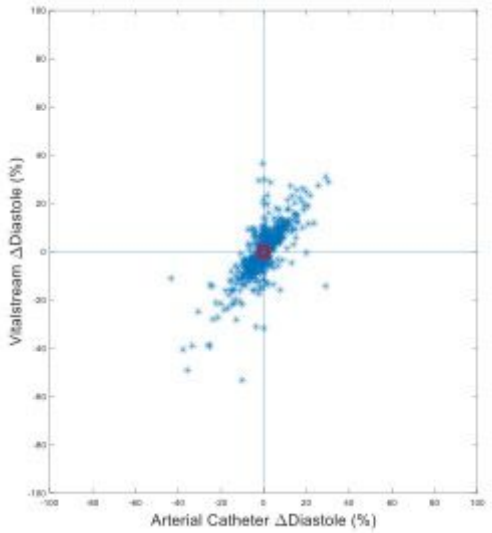

Figure 5

Result of trend analysis of discrete TD comparisons. Concordance: 0.85 with 15% exclusion window