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Performance evaluation of non-invasive cardiac output monitoring device (HemoVista) based on multi-channel thoracic impedance plethysmography technology

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Background: A non-invasive method of measuring cardiac output (CO) can be beneficial in the care of critically ill patients. HemoVista (BiLab Co., Ltd.) is a medical device that measures CO non-invasively using multi-channel impedance plethysmography technology. The purpose of this study was to exploratively evaluate the performance of HemoVista in critically ill patients undergoing CO monitoring with the FloTrac (Edwards Lifesciences).

Methods: After non-invasively installing the HemoVista sensor in critically ill patients whose CO was monitored with the FloTrac, CO values measured by both devices were collected for 30 minutes. Cardiac output measured by both devices was selected every 10 seconds, creating approximately 360 data pairs per patient. Linear correlation analysis with Pearson correlation coefficients, Bland-Altman analysis, and four-quadrant plot analysis were performed to evaluate the performance of HemoVista.

Results: A total of 7,138 pairs of CO data from the 20 patients were included in the analysis. A significant correlation was observed between the two methods of measuring CO (Pearson's r=0.489, P<0.001). The mean bias was 1.03 L/min, the 95% CI for the limit of agreement was −1.83 L/min to 3.93 L/min and the percentage error was 55.8%. The concordance rate of time-dependent CO between the two devices was 14.6%.

Conclusions: It was observed that the current version of HemoVista has unsuitable performance for use in intensive care units. To be used for critically ill patients, the algorithm must be improved and reevaluated with an enhanced version.

Key Words: cardiac output; critical care; impedance cardiography; transthoracic impedance

Original Article

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INTRODUCTION

Continuous hemodynamic monitoring is crucial for the care of the critically ill patients, making invasive hemodynamic monitoring common in intensive care units (ICUs). Monitoring hemodynamic parameters, such as cardiac output (CO), is particularly useful for distinguishing the cause of hemodynamic instability and guiding fluid management and vasopressor/inotropic support [1]. Thermodilution using a Swan-Ganz catheter has become the gold

standard method for CO monitoring, but it is not actively used in clinical practice because it is too invasive [2]. The existence of many less invasive alternatives is another reason why pulmonary artery catheters are not routinely used in critically ill patients [3].

Although several less invasive devices to measure CO have been commercialized, FloTrac/Vigileo system (FloTrac, Edwards Lifesciences) is widely used in Korea. The FloTrac uses arterial pressure waveform analysis to calculate CO and does not require calibration [4]. Excluding patients with septic shock, advanced liver disease, irregular heart rhythm, or severe aortic stenosis, the performance of FloTrac in relatively stable patients has been verified in several studies, ensuring its clinical usability [4,5]. However, because the FloTrac is also a minimally invasive method, it is not completely free from complications such as infection, nerve injury, and thrombus formation [6]. If a method that can monitor CO non-invasive manner is applied, it may be beneficial in managing critically ill patients.

HemoVista (BiLab Co., Ltd.) is a medical device that can measure CO non-invasively using multi-channel impedance plethysmography technology and has received medical device approval from the Ministry of Food and Drug Safety (MFDS) of Korea. However, approval by the MFDS does not necessarily guarantee the clinical accuracy of the medical device. Several attempts have been made to measure CO non-invasively, but they have not shown sufficient performance to replace invasive methods [7]. The percentage error in stroke volume of HemoVista compared to the pulse contour analysis method in a swine model was 11%, indicating good performance [8]. However, the performance of this device needs to be evaluated in patients. The purpose of this study was to exploratively evaluate the performance of HemoVista in critically ill patients undergoing CO monitoring with the FloTrac.

MATERIALS AND METHODS

This study is a single-center exploratory prospective comparative observational study. It was approved by the Institutional Review Board of Asan Medical Center (Seoul, Korea; No. 2023-0564; approval date: May 17, 2023) and registered with an international clinical trials registry platform (http://cris.nih.go.kr; KCT0008487, principal investigator: Byung-Moon Choi, date of registration: June 1, 2023) before the enrollment of the first participant. Written informed consent was obtained from the patient's representative.

KEY MESSAGES

- Continuous assessment of cardiac output (CO) is helpful in the care of the critically ill patients.
- HemoVista is a real-time and continuous non-invasive CO monitoring device based on multi-channel impedance plethysmography technology.
- Compared to the CO measured with FloTrac, the CO measured with HemoVista was generally lower.
- The performance error in Blant-Altman analysis was large (percentage error, 55.8%), indicating that improvement of the algorithm is necessary for clinical application.

Study Population

Patients aged 20 years or older undergoing CO monitoring with FloTrac in the ICU were enrolled. Patients were excluded from the study for any of the following reasons: significant arrhythmia that may affect stroke volume calculation, presence of pacemaker, use of mechanical circulatory support devices such as extracorporeal membrane oxygenation or intra-aortic balloon pump, and skin lesions at the HemoVista sensor placement site.

Study Procedure

After the patient was registered, a researcher (JP) visited the ICU and attached the HemoVista sensor to the patient. Before attaching the sensor, the attachment area was thoroughly cleaned with an alcohol swab. A photo of the sensor (ePAD) attached to an actual patient and the HemoVista main body display screen are shown in Figure 1. The sensor connection part, which connects to the HemoVista equipment, can be located either below or above the nipple. The electrode 1 should be placed as close to the nipple as possible, electrodes 2 and 3 should be placed on both anterior axillary lines, and electrode 4, which corresponds to the ground electrode, can be attached anywhere on the skin. After the device internally confirms that the sensor is well placed and calibrated for about 2 minutes, the CO value is displayed. RS232 cables were connected to each of the FloTrac and HemoVista devices and then to a PC with software installed to download data (AsanAMS ver 1.3.4, Asan Medical Center). The time-synchronized and downloaded data were analyzed retrospectively.

Data Collection

After confirming that the patient's hemodynamics were as sta-

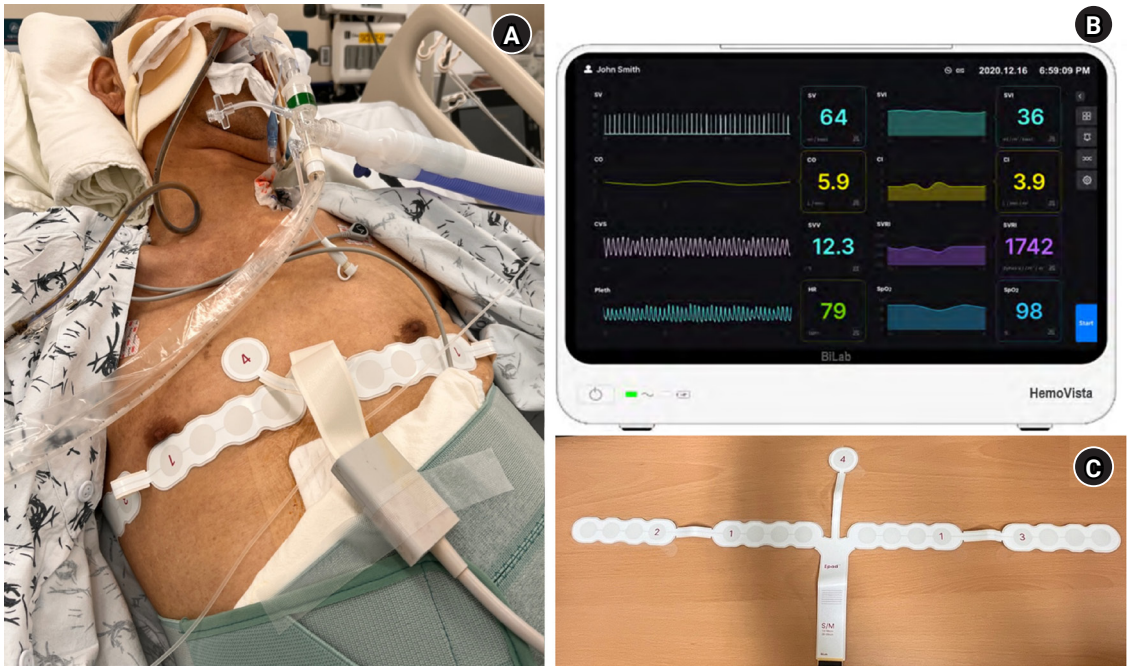

Figure 1. Test device and related sensor (ePAD). HemoVista (BiLab Co., Ltd.) was used as a test device to noninvasively measure cardiac output. (A) Practical situations of cardiac output measurement with HemoVista in a critically ill patient. (B) An example of the operating screen of the HemoVista device. (C) A HemoVista sensor.

ble as possible, CO values measured by FloTrac and HemoVista were collected for approximately 30 minutes. Cardiac output measured by both devices was selected every 10 seconds, creating approximately 360 data pairs per patient. Data from periods in which CO values were not measured by HemoVista due to noise or other reasons were excluded from the analysis. Additionally, if the CO value showed a difference of more than 50% compared to the previous value within 1 minute and then returned to the previous value, the values were judged to be outliers and excluded from the analysis. Patients were assigned numerical codes instead of their hospital IDs to ensure the confidentiality of personal information. Data related to the patient's physical characteristics and interpretation of research results were collected. The collected items include age, sex, weight, height, Sequential Organ Failure Assessment (SOFA) score, comorbidities, hemoglobin, continuous renal replacement therapy, pleural effusion, mechanical ventilation, blood pressure, heart rate, vasopressors and inotropic drugs.

Data Analysis

Pairs of CO data measured with FloTrac and HemoVista were evaluated for correlation using Pearson correlation and simple linear regression. The agreement between the two measurement methods was evaluated using Bland-Altman analysis [9]. Bias was defined as the average of the differences in CO measured between the reference device and the test device. Limits of agreement were calculated as "mean difference±1.96×standard deviation." A percentage error (within 2 standard deviations of the bias divided by the mean of the reference measurements) was used to evaluate accuracy [10]. If the percentage error was less than 30%, the test measurement method was considered interchangeable with the reference method [11]. A four-quadrant plot was used to evaluate the ability to track changes [12]. Because CO changes over time, evaluating the performance of a novel CO-monitoring device requires assessing trend changes as well as accuracy and precision [12]. The concordance rate, defined as the ratio (percentage) of CO measurements assessed by the test method and the reference method that change correctly in the same direction (decrease or increase) to the sum of all changes, was calculated to evaluate the trending ability. The absolute change less than 0.25 L/min was set as the exclusion zone.

Statistical Analysis

Because the study was designed to explore the performance of a new CO-monitoring device rather than a confirmatory study to test a specific hypothesis, no sample size was calculated, and subjects within a realistically feasible range were

enrolled. All statistical analyses were performed using the SigmaStat software version 3.5 for Windows (Systat Software, Inc.) or GraphPad Prism version 10.2.2 for Windows (Dotmatics). Normally distributed continuous variables are presented as mean±standard deviation. Non-normally distributed continuous variables are presented as medians (25%–75%). Categorical variables are presented as counts and percentages. P-values <0.05 were considered statistically significant.

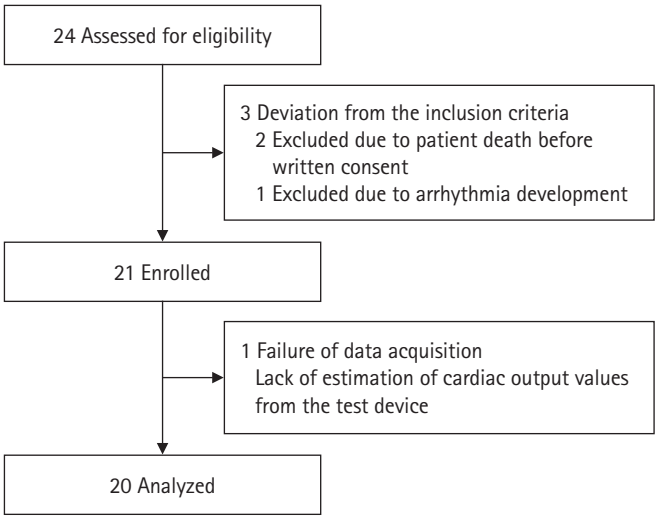

Figure 2. Consort diagram. A total of 24 patients were screened, and of these, three patients were excluded due to violations of the inclusion criteria. A total of 21 patients were enrolled in this study, and one patient dropped out from the study because of the lack of estimation of cardiac output values from the test device. Hence, 20 patients were included in the analyses.

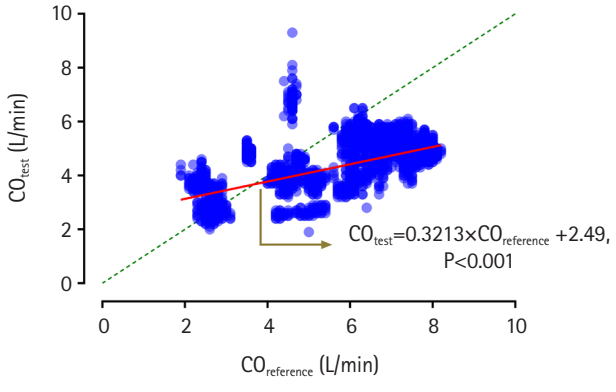

Figure 3. Cardiac output (CO) values measured with the test device (HemoVista) and reference device (FloTrac). The green dotted line indicates the line of identity. The red solid line is the simple regression line.

RESULTS

A consort diagram of participants is shown in Figure 2. A total of 20 patients were included in the analysis, and their physical characteristics are summarized in Table 1. After excluding 12 data pairs determined to be outliers (ID4: 2, ID5: 9, ID20: 1), a total of 7,138 pairs of CO data were included in the analysis. Cardiac output values measured with HemoVista (test device) and FloTrac (reference device) are presented in Figure 3. There was a significant correlation between the CO values measured by the two devices (Pearson r=0.489, P<0.001), but in general, the values of the HemoVista tended to be lower than those of the FloTrac. A Bland-Altman plot describing agreement between the two measurements is depicted in Figure 4. The

Table 1. Patient characteristics

Variable	Value (n=20)
Age (yr)	68 (62–73)
Sex (male:female)	14:6
Weight (kg)	70.1±13.1
Height (cm)	164.4±9.3
Body mass index (kg/m^2)	24.2 (23.3–29.0)
SOFA score	13 (12–16)
Hemoglobin (g/dl)	8.5 (8.1–9.3)
Comorbidities (multiple answers possible)	
Hypertension	7
Diabetes mellitus	8
Congestive heart failure	6
Patients receiving CRRT	3
Patients with pleural edema observed on chest x-ray	15
Patients with pleural effusion observed on chest x-ray	18
Patients with pneumonia receiving antibiotics	6
Patients receiving mechanical ventilation	20
Tidal volume (ml)	425 (350-500)
Patient undergoing sedation	19
Hemodynamic status during data collection	
Systolic blood pressure (mm Hg)	118.5 (100.0-133.5)
Diastolic blood pressure (mm Hg)	61.0 (52.8-67.5)
Mean blood pressure (mm Hg)	79.0 (69.0-88.3)
Heart rate (beats/min)	84.0 (71.0-92)
Patients receiving vasopressors or inotropic drugs	
Norepinephrine	19
Vasopressin	7
Epinephrine	1
Dobutamine	1

Values are presented as median (interquartile range), number, or mean± standard deviation.
SOFA: Sequential Organ Failure Assessment; CRRT: continuous renal replacement therapy.

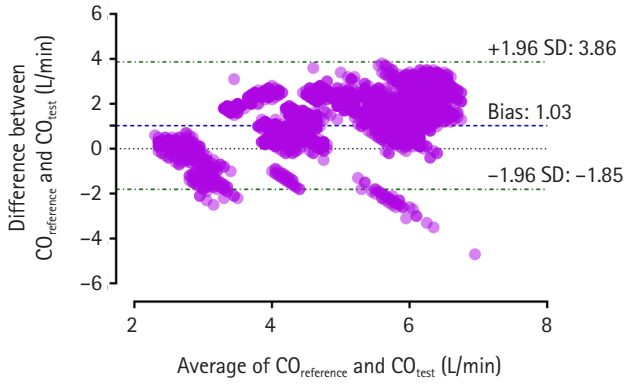

Figure 4. Bland-Altman plot of cardiac output (CO) measured by two devices (test: HemoVista, reference: FloTrac). Bias was defined as the average of the differences in CO measured between the reference device and the test device. The percentage error was 55.8%. SD: standard deviation.

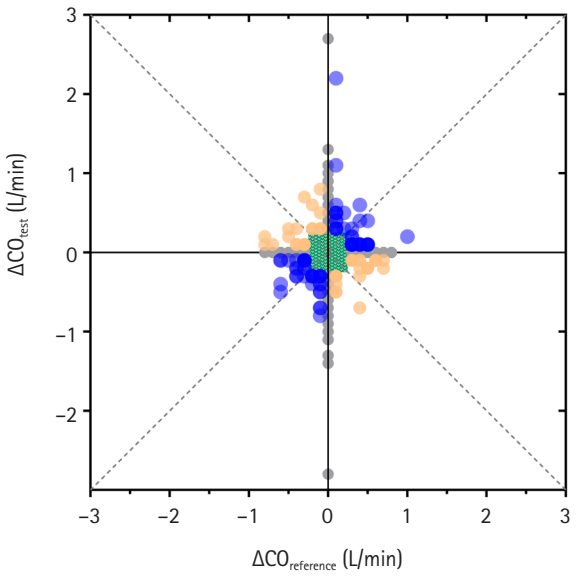

Figure 5. Four-quadrant plots of cardiac output (CO). The values on the horizontal axis refer to ΔCO values of the reference device (FloTrac), whereas the vertical axis refers to the ΔCO values of the test device (HemoVista). ΔCO values mean differences between consecutively obtained CO values. The central green square refers to the exclusion zone (range, −0.25 to 0.25 L/min). Because very small ΔCO values should not be included in the trending analysis, and, thus, a central exclusion zone is applied.

percentage error was 55.8%, which suggests that it is difficult to immediately use HemoVista in critically ill patients, even considering that FloTrac is not the gold standard method for CO. Among the 7,117 data pairs of CO change, 6,609 data pairs in the range of −0.25 to 0.25 L/min were excluded, and a 4-quadrant plot was generated with the remaining 508 data pairs (Figure 5). The concordance rate was 14.6% (=74/508×100), indicating that the trending ability is very low.

DISCUSSION

Cardiac output measured with HemoVista, a noninvasive hemodynamic monitoring device, was observed to be generally lower than that with FloTrac. The agreement between the two devices evaluated by Bland-Altman analysis was not high, and the ability to track changes evaluated by four-quadrant plot was also low.

Cardiac output measurement methods can be classified into three types based on their degree of invasiveness: invasive, minimally invasive, and non-invasive. FloTrac, launched in 2005, is a minimally invasive device that measures CO using pulse contour analysis. Because it requires only an arterial catheter and does not need calibration, it is widely used, particularly in Korean clinical settings. Several studies comparing the performance of FloTrac with that of a pulmonary artery catheter have shown good correlation [13], but its accuracy is known to be poor under certain conditions [4]. HemoVista is a catheter-free, real-time continuous CO monitoring device. Since it is non-invasive and uses a disposable electrode pad, it eliminates the risk of infection. However, like other non-invasive devices, its accuracy may be lower than that of invasive devices [14].

Bioimpedance refers to the voltage response of tissue to an externally applied alternating electric current (AC). Thoracic electric impedance exhibits time-dependent changes synchronized with lung ventilation and cardiac contraction, enabling its use for non-invasive monitoring of regional lung ventilation and cardiac perfusion [15]. The methods for calculating stroke volume from impedance cardiography have been adjusted, and various electrode arrays and software have been developed [16,17], but the performance was still not established enough even in commercialized bioimpedance devices. A meta-analysis about impedance CO monitoring showed inadequate percentage error (mean percentage error were 48% in adult patients and 42% in pediatrics) and high inter-study heterogeneity [18]. In a systemic review that evaluated bioimpedance and bioreactance CO in neonates, the percentage error ranged between 5.3% to 71.6%, with only 5 of the 14 included studies reporting a percentage error ≤30% [19].

HemoVista is a new multi-channel impedance plethysmog-

raphy device equipped with 16 electrodes that uses lead-forming methods, a type of spatial filtering. Impedance plethysmography is used to measure changes in volume associated with changes in electrical impedance. The HemoVista injected current between a chosen neighboring electrode pair. For each current injection, 16 voltage data were measured simultaneously (parallel measurements). Thirteen of them were used for stroke volume calculations and 3 were used to estimate electrode-skin contact impedance values. This was repeated for all 16 neighboring current-injecting electrode pairs in 10 ms. Therefore, for every 10 ms, 208 (13×16) impedance data were measured for stroke volume calculations [20]. Previous multilead impedance cardiography systems used transthoracic impedance data to produce cross-sectional images of the heart and estimated stroke volume from these images [15]. However, HemoVista does not reconstruct images. Instead, it employs a lead-forming method to separate cardiac volume signal changes from respiratory volume signal, synchronized with a separately-acquired ECG signal. The cardiac volume signal change is assumed to be proportional to the stroke volume [21]. The heart rate is then multiplied by the stroke volume to obtain cardiac output (CO = SV × HR).

The main reason why HemoVista showed a high percentage error and low concordance rate may be that critically ill patients were not included in the algorithm development process. Since the algorithm was primarily developed for healthy adults, it appears to have performed poorly in estimating stroke volume in critically ill patients, such as those with pleural effusion or pneumonia, which can affect bioimpedance measurements. Estimation of stroke volume from thoracic impedance is based on the assumption that changes in stroke volume are proportional to changes in cardiac impedance signals. Therefore, factors such as skin-electrode impedance and lung conductivity, which can affect thoracic impedance signals, may influence the estimation of stroke volume [21]. The percentage error was calculated according to the presence or absence of pulmonary edema, pleural effusion, and pneumonia. The percentage error was higher in patients with pulmonary edema (64%) than in those without (48%), suggesting that pulmonary edema affects the thoracic impedance signal. However, percentage errors in patients with pleural effusion and/or pneumonia were similar with pleural effusion ([56%] and without [56%], and with pneumonia [58%] and without [60%]).

There are several limitations to this study. First, a gold standard reference device, such as a pulmonary artery catheter or echocardiograph, was not selected. The FloTrac system used in this study cannot be considered a gold standard for measuring CO in the strictest sense. Without an appropriate reference device, it is difficult to rule out the possibility that the performance evaluation results of a newly developed CO measurement device may be unreliable. However, the practical challenges of establishing a gold standard reference device must also be considered. Due to the highly invasive nature of pulmonary artery catheters, their use in clinical settings is limited [2]. Although transthoracic echocardiography or transesophageal echocardiography offers the advantage of being noninvasive, they are not realistically feasible for research purposes in critically ill patients. When measuring CO using transthoracic echocardiography, it is recommended that the patient remain in the lateral decubitus position, but it was difficult to maintain this position for 30 minutes in critically ill patients on mechanical ventilation. Transesophageal echocardiography could address these issues, but the high cost of the research prescription set by the hospital made it impossible to cover with research funds. Therefore, as an alternative, we conducted the study on critically ill patients who were being monitored with FloTrac for clinical purposes. A previous study demonstrated that FloTrac measurements were comparable to those obtained via echocardiography, suggesting that it could be used to monitor CO in critically ill patients [5]. Additionally, it appears that FloTrac could serve as a reference device in critically ill patients, provided that those with certain conditions known to cause inaccuracies (e.g., sepsis, advanced liver disease) are excluded [4]. Indeed, patients with conditions known to cause inaccuracies in FloTrac measurements were not included in this study. However, when interpreting the results obtained using FloTrac as a reference device, these limitations must be fully considered, and conclusions should be drawn with caution. Second, the patients enrolled in this study were not selected from a specific disease group, but rather were heterogeneous in their characteristics. In terms of performance evaluation, homogeneous patient characteristics can be helpful for objective assessment. In particular, it is difficult to rule out the possibility that the performance of HemoVista™ was somewhat lower because many patients (75%) had pulmonary edema, which can affect bioimpedance measurements. However, evaluating a diverse patient population that reflects actual clinical settings may be more meaningful.

In conclusion, even considering the limitations of not using a pulmonary artery catheter or echocardiography as reference devices, the performance of HemoVista was inadequate

for CO monitoring in critically ill patients. The CO measured with HemoVista was generally lower compared to that measured with FloTrac. Additionally, the performance error in the Bland-Altman analysis was large (percentage error, 55.8%), and the ability to track changes, as evaluated by a four-quadrant plot, was low (concordance rate, 14.6%). To use HemoVista effectively in critically ill patients, its algorithm must be improved, and the performance of the improved HemoVista should be evaluated with an appropriate reference device.

CONFLICT OF INTEREST

No potential conflict of interest relevant to this article was reported.

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AUTHOR CONTRIBUTIONS

Conceptualization: BMC. Data curation: JP. Formal analysis: JP. Methodology: BMC. Project administration: BMC. Visualization: JP. Writing – original draft: JP. Writing – review & editing: all authors. All authors read and agreed to the published version of the manuscript.

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