A NOVEL APPROACH TO MEASURE CARDIAC OUTPUT NONINVASIVELY: A COMPARISON WITH THE THERMODILUTION METHOD ON CRITICAL CARE PATIENTS

John Kabal, MD, PhD and Bruce K. Lagerman, BSE, JD

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ABSTRACT. Objective. To compare the accuracy and reliability of cardiac output (CO) measurement by a Noninvasive Hemodynamic Analyzer (NHA) to the thermodilution cardiac output (CO_{TD}) technique in ICU patients of cardiac condition. **Method.** ICU retrospective data collected in a 700-bed university-affiliated regional medical center. The data results from 203 patients who required invasive hemodynamic monitoring for clinical and/or surgical management. **Results.** The ranges of the two CO measurements were: CO_{TD} = 2.06 to 8.8 l/min and CO_{NHA} = 2.06 to 8.46 l/min, respectively. The Mean and SD of CO_{NHA} = 4.819 l/min +/–1.053 was near to CO_{TD} = 4.902 l/min +/–1.421. Variance was better for CO_{NHA} = 1.110 l/min compared to CO_{TD} = 1.421 l/min. Median of CO_{NHA} showed 4.813 l/min and CO_{TD} = 4.660 l/min. Bias was 0.083 l/min with 95% Confidence Interval (Precision): –0.26 to 0.040, and 95% Limits of Agreement was between –1.661 to 1.827 l/min. **Conclusions.** The results of this retrospective study indicate that the CO_{NHA} technique may be a promising screening method. Additional studies are needed to explore its diagnostic trending capability. This noninvasive CO technique has been proven to be clinically accurate and may be applicable for telemedicine applications.

KEY WORDS. Noninvasive cardiac output, clinical decision system, thermodilution, critical care.

INTRODUCTION

The critical importance of cardiac output (CO) to properly diagnose and treat cardiovascular problems has made it a long-time primary research target. Once CO is known, a whole sequence of hemodynamic parameters can be calculated. Since the introduction of the Swan–Ganz pulmonary artery catheter [1], the thermodilution method [2] has become the most frequently used clinical reference "gold standard" method against which other CO measurement methods are compared.

CO measurement does not require an invasive approach. In fact, several noninvasive techniques were developed in recent decades [3–6]. All of them have brought along well-known significant drawbacks, which keep alive the worthwhile pursuit of more accurate noninvasive CO methods.

In this presentation, we describe a clinical decision system, a Noninvasive Hemodynamic Analyzer (NHA), which develops and manipulates simulation models of complex physiological problems. The NHA is capable of computing CO by using vital signs and anthropological data as a computerized decision system. The approach to measure CO from vital signs, specifically pulse pressure

From the Reston Noninvasive Hemodynamic Center 1712 Clubhouse Road, Suite 103 Reston, Virginia 20190, U.S.A.

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Address correspondence to John Kabal, Reston Noninvasive Hemodynamic Center, 1712 Clubhouse Road, Suite 103, Reston, Virginia 20190, U.S.A.
E-mail: lagerman@attglobal.net

noninvasively, had remained unsuccessful for many years and only recently became a reality. The pulse contour analysis technique was introduced to measure CO by using pulse pressure. However, pulse pressure provides only relative changes in CO; therefore, the measurement must be calibrated each time to CO_{TD} [7].

We overcame this challenge and avoided standardization by creating two algorithmic sequences, with the input of vital signs and anthropological data. In the first algorithmic sequence, the proverbial fix point (the laws of levers and pulleys by Archimedes) was the physiological fact that we are able to calculate the ideal systolic, diastolic, mean arterial, and pulse pressure values of an adult (>18 years old) between the rest and maximum heart rates. The possibility of computing the Ideal Pulse Pressure led to the conception (and scientific base) of obtaining an Ideal CO at different heart rates. The Actual CO was calculated by "adjusting" the difference to the Ideal CO. For the purpose of this paper, we have provided only a general description about this technique as it relates to the scope of our research.

One of the important features of this method is that retrospective analysis can be performed. If the static and dynamic characteristics of the patient are available, the CO_{NHA} can be computed independently of time, place, and instrument of when the actual measurements were taken. For our retrospective study between CO_{TD} and CO_{NHA}, we obtained the static and dynamic characteristics, and the CO_{TD} values, of 203 randomly selected Intensive Care Unit (ICU) patients from the database at the Inova Fairfax Hospital Cardiac Catheterization Laboratory located in Falls Church, Virginia.

The objective of this study is to compute noninvasively CO of the ICU patients, using their particular hospital data and then to calculate the clinical accuracy of the CO_{NHA} to their corresponding CO_{TD} values.

METHOD

Description of thermodilution technique [8]

A closed injection system was used with an in-line injectate thermistor, 10 ml boluses of room temperature D_5W was rapidly injected into the right atrium, using the proximal port of a thermodilution pulmonary catheter. For patients in sinus rhythm, at least three serial measurements were obtained without regard to the point in the respiratory cycle that the injections were made. For patients in irregular rhythms, such as atrial fibrillation, five serial measurements were obtained. The resultant curves were analyzed using a cardiac output computer (Model 3300 Abbott Critical Care Systems) and reported as the mean of the measurements obtained.

Description of the noninvasive hemodynamic analyzer (NHA) technique

The NHA applies two algorithm cascades to obtain the actual stroke volume (Actual SV) and the corresponding hemodynamic profile of a particular adult patient. In this paper, this hemodynamic aspect is not presented. Through the first cascade of algorithms, the ideal stroke volume was calculated. In the second cascade of algorithms the Actual SV was computed by an adjustment constant relative to the corresponding ideal stroke volume.

To calculate the ideal stroke volume of a particular patient, the following physiological correlation is utilized:

(a) Max. Ideal Pressure Rate Product (PRP) = Systolic Blood Pressure (SBP) × Heart Rate/100 is plotted against the %max. HR (Sex dependent: male = 333 and female = 294)
(b) Max. HR can be obtained by using regression coefficients according to age and sex
(c) Normal HR in resting state is assumed to be 40% calculated max. HR
(d) From the max. Ideal PRP the ideal SBP values can be calculated for any particular HR

$$\begin{aligned} PRP &= (SBP \times HR)/100 \rightarrow SBP \\ &= (PRP \times 100)/HR \end{aligned}$$

(e) To maintain a physiologically optimal oxygenated blood supply for the vital organs, such as the brain and heart, a constant opening blood pressure is required, Mean Arterial Pressure (MAP), and this pressure is maintained by a cascade of sophisticated biofeedback. Normal MAP is age dependent and accordingly the scale for males is 84–100 mmHg and for females is 81–97 mmHg. Considering that MAP is the geometric average of pulse area between SBP and DBP (an approximate triangle):

$$MAP = [(SBP - DBP)/3] + DBP$$

(f) $$DBP = MAP - [(SBP - MAP)/2]$$

(g) Thus through steps (a) to (f), an ideal SBP and DBP, including ideal Pulse Pressure (PP) can be computed according to the corresponding HR, as ideal dynamic parameters.
(h) With the above-obtained dynamic and static characteristics, such as patient's age, height, body weight (frame), an ideal Stroke Volume (SV) can be computed by a series of equations.

The calculation of SV is based upon a theoretical model of Pulse Wave (PW). In the aorta and/or blood vessels,

the manifestation of SBP as a pulse wave originates by the constriction of the left ventricle (systole). Although the values are different at the aortic level, the resulting MAP is practically the same at the cubital area, where the blood pressure is actually measured.

The true SV can be measured only in the ascending aorta. However, the portion of the blood volume, which creates the PW in the peripheral major vessels is synchronous in time (pulse rate) with the bolus of the SV. The PW is the result of the oscillation of the SBP and DBP and their difference at the largest expansion is equal to PP. Calculating the PP-Ratio

$$(\mathrm{PP} - \mathrm{R}) = (\mathrm{SBP} - \mathrm{DBP}/(60/\mathrm{HR}))$$

We can take this result empirically as the largest circumferential extension of the blood vessel.

If we assume that the PP−R is essentially the circumferential change of $\mathrm{PW} = 2\mathrm{r} \times \pi$, we can calculate the area, equal to $\mathrm{r}^2 \times \pi$, therefore

$$\mathrm{r} = (\mathrm{PP} - \mathrm{R})/2 \times \pi \rightarrow [((\mathrm{PP} - \mathrm{R})/2 \times \pi)^2 \times \pi]$$

The goal in this case is to calculate the Pulse Wave Volume (PW−V), so the approximate propagated bolus size (blood volume increase) will be equal to

$$\mathrm{PW} - \mathrm{V} = [(\mathrm{PP} - \mathrm{R}/2 \times \pi)^2 \times \pi]/(60/\mathrm{HR})$$

Multiplying the above equation by a floating factor and taking the square root value, a so-called ideal SV is empirically computed and is divided by the Body Surface Area (BSA), and the ideal Stroke Index (SI) can be obtained. Finally, multiplying both parameters with the actual heart rate, CO and/or CI are acquired. The floating factor makes it possible to have a steady CI of approximately 3.5 l/min/m^2 irrespective of age or sex. The Actual SV is calculated in the same manner, but is corrected by an adjustment constant to obtain its true SV value at the actual heart rate.

A flowchart of the NHA clinical decision system computing CO is represented in Figure 1. This schematic presentation is only intended to provide a general understanding of computing the $\mathrm{CO_{NHA}}$.

DATABANK

Collection of vital signs

Hemodynamic measurements (Heart Rate, Systolic and Diastolic Pressure) were acquired, recorded, and analyzed using the Quinton Qcath Physiologic Monitoring System. A fluid-filled line with a pressure transducer (Abbott Critical Care System) leveled to 5 cm below the sternal angle was used for all invasive blood pressure measurements. In contrast to the serial measurements and averaged CO data, for this study only one vital sign set was available for the computation.

Description of patient population

All data of 203 patients were collected for this study from the ICU of Inova Fairfax Hospital, a university-affiliated 700-bed regional medical center in Northern Virginia. Patients' diagnoses are presented in Table 1.

Patients were randomly selected by age (over 18 years old) and diagnostic stratification (only cardiac patients were included) (Table 2). The dataset of these ICU patients were randomly collected from the previous year. The duration and time-sequence of collection depended upon the necessary amounts of samples.

No information was available and/or collected about the duration of their hospital stay, respiratory set-up, or pre/postoperative conditions.

RESULTS

Cardiac Output is the most important hemodynamic value in the parameters of hemodynamic hierarchy. Therefore, any new CO technique should be proven clinically accurate and reproducible before being applied in any clinical decision making. Traditionally, every new method is compared with one of the invasive "gold standards" namely the Fick, thermodilution, and dye dilution techniques [9, 10, 11]. Clinically, the thermodilution CO technique is preferred over the technically more demanding Fick CO technique, despite the fact that the latter method is more precise.

In this study, the noninvasive $\mathrm{CO_{NHA}}$ method was compared to the invasive thermodilution $\mathrm{CO_{TD}}$ technique (Table 3). For statistical evaluation, we used "Analyse It" [12], an advanced comparative and clinical statistical software program:

(a) To demonstrate the variability and presence of a continuous scale; and
(b) To compare the two methods for bias and identify any relationship between imprecision and concentration by the Bland–Altman Plot [13].

Comparison of the $\mathrm{CO_{TD}}$ and the $\mathrm{CO_{NHA}}$ datasets shows insignificant differences between the two

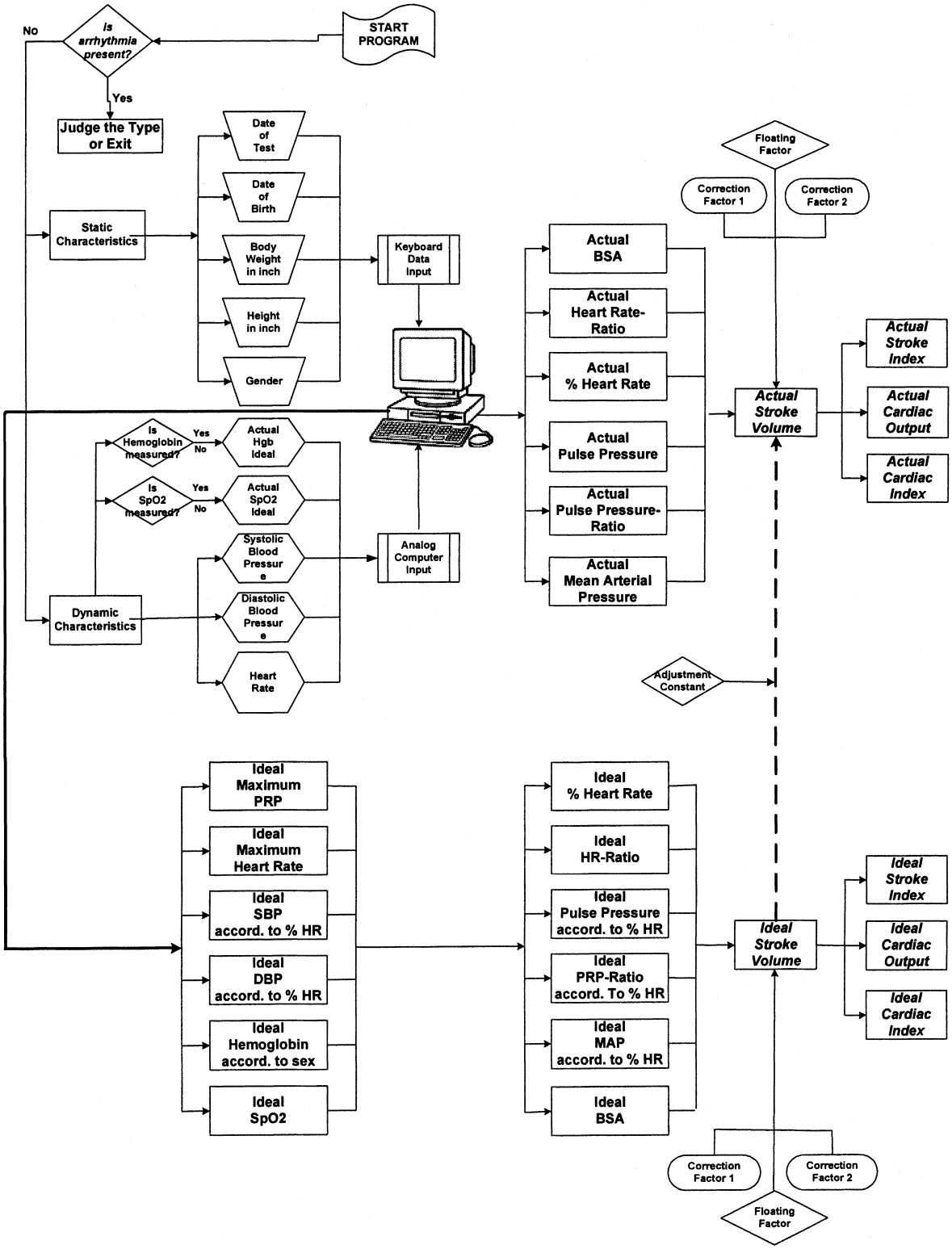

Fig. 1. Cardiovascular clinical decision system: Flowchart of the noninvasive hemodynamic analyzer (NHA).

Table 1. Cardiopulmonary diagnoses of the ICU patients participating in the retrospective study

	Coronary artery disorder	Cardio-myopathy	Valvular disease	Pulmonary hypertension	Congenital	Transplant	Unknown
Male							
(128)	66	8	37	0	2	10	5
%	51.56	6.25	28.91	0	1.56	7.81	3.91
Female							
(75)	42	7	15	3	0	7	1
%	6.0	9.33	20.0	4.0	0	9.33	1.33
Total (203)	108	15	52	3	2	17	6
%	53.2	7.39	25.62	1.48	0.99	8.37	3.96

Note. Demographic data (age, gender, height, and body weight) and vital signs, such as, SBP, DBP, and HR were collected from the patient's chart, without the possibility of disclosing the patient's identity (Table 2).

Table 2. Vital signs and demographic conditions of the participating patients

	SBP (mmHg)	DBP (mmHg)	MAP (mmHg)	PP (mmHg)	HR (beats/min)	Age (years)	Height (cm)	BW (kg)	BSA (m^2)
Male (128)									
Average	129	70	90	59	76	61.2	176.7	85.0	2.02
SD	24	13	14	22	17	13.8	7.3	15.7	0.18
Minimum	77	41	54	13	47	14.9	54.9	52.2	1.60
Maximum	202	101	130	119	129	86.0	195.6	154.2	2.67
Female (75)									
Average	133	68	90	65	83	62.9	160.3	69.5	1.72
SD	27	13	16	24	15	13.0	7.4	18.0	0.21
Minimum	85	36	56	19	53	22.3	134.6	40.8	1.26
Maximum	193	95	116	133	129	88.4	177.8	134.3	2.44

Note. SBP = Systolic Blood Pressure; DBP = Diastolic Blood Pressure; MAP = Mean Arterial Pressure; PP = Pulse Pressure; HR = Heart Rate; BW = Body Weight; BSA = Body Surface Area.

Table 3. Comparison of the CO_{TD} and CO_{NHA} datasets obtained by retrospective study

	CO_{TD}	CO_{NHA}
Range (6.74 l/min)	2.06 to 8.8 l/min	2. 06 to 8.46 l/min
Mean	4.902 l/min	4.813 l/min
95% Confidence interval	4.737 to 5.0674	4.673 to 4.965
SD	1.1920 l/min	1.0535 l/min
Variance	1.4208 l/min	1.1098 l/min
Coefficient of variation(%)	24	22

measurements, although the Variance is better in the case of CO_{NHA}.

The Bland–Altman Plot (Table 4, Figure 2.) demonstrates other aspects of agreement. They are a) **Bias** (the extent to which the new method under- or overestimates the "gold standard")[13] and b) **Precision** (the range of the values that encompasses 95% of the values obtained). The smaller the bias and narrower the range between the

Table 4. Summary of the Bland-Altman plot [CO_{TD} and CO_{NHA}]

Bias	−0.083 l/min
Precision (95% Confidence interval)	−0.206 to 0.040 l/min
Agreement (95% Limits of agreement)	−1.827 to 1.661l/min (within ±2 SD)
95% Difference between methods	∼30% to ∼49%

upper and lower limits (the two standard deviation (SD) of the mean differences), the greater the agreement of the two measurements.

In our evaluation, despite the questionable time synchronization of the two CO measurements, we found that 93% of the population was within ±30%. The 7% discrepancy appears evenly distributed in the minus range and may be due to inadequate synchronization of vital signs (one measurement) against the average three CO_{TD} measurements. In the case of occasional atrial fibrillation, the average of five CO_{TD} measurements were used. However, we were not able to obtain any information to identify these patients.

Our literature survey [14–25] indicates that the obtained accuracy is very encouraging (Table 5.).

In the best case, the "gold standard" CO_{TD} technique could be in error with ±10% compared to the Fick CO technique and, in general, ±20% is routine use due to technical and human errors [26]. These facts indicate that the trending capability, accuracy, and reproducibility are sine qua non for any noninvasive CO methods.

The result of a recent meta-analysis revealed that the two most frequently used noninvasive CO techniques [27]: Bioimpedance and Doppler ultrasound, showed overall limits of agreement of 15–82% and ±65%. This same study has also proposed that an error of ±30% maximum may be acceptable for the difference between the new method and thermodilution. It is worth noting that the literature does not always provide complete information about the results of Bland–Altman Plot, namely, Bias, Precision, Accuracy, and the % Difference between the two methods.

DISCUSSION

The most important role of CO in the hemodynamic hierarchy is to regulate blood flow and pressure distribution by an integrated function and thereby to maintain an adequate oxygen transport at the organ/cellular level [28, 29]. The key position of oxygen transport in different clinical conditions makes it critical to measure the cascade of hemodynamic balance, but without the CO, these hemodynamic parameters cannot be obtained.

The hospital-based invasive "gold standard" is frequently challenged by new noninvasive CO techniques, but so far not one can replace the (cumbersome, rather complicated, expensive, and sometimes life-threatening) thermodilution technique. The CO_{NHA} technique is analogous to these other noninvasive CO techniques, but with new properties and/or capabilities. However, this study is only the first in a series of future planned studies.

The results of this retrospective study prove that the CO_{NHA}technique is producing clinically acceptable data in low, normal, and high CO states. This fact is significant for the following four reasons:

(a) The cardiopulmonary diagnoses of patients were in seven different categories,
(b) The vital signs, namely SBP, DBP, and heart rate showed a high range of fluctuation,
(c) The patients' demographic distribution, of age, height, and body weight in both genders varied widely, and
(d) The vital signs data compromised a singular set as compared to the averaged CO_{TD} values.

This new technique has the potential of appropriate continuity, which is important to trend progress in the disease process or following of treatment(s). Its application does not require training for data collection/standardization and does not cause safety risk for the patient. This noninvasive technique is easily altered to an invasive approach which is also unprecedented as compared to the other methods. Without any restrictions, it can be used in environments such as an ambulatory office setting or in an operating room. From the viewpoint of healthcare, the NHA method is inexpensive and cost effective.

We conclude that the capacity of the NHA technique may be an invaluable healthcare tool as a screening device. Because the vital signs collection can be independent from the physical presence of the NHA, this method also could be ideally applied in telemedicine applications.

LIMITATIONS OF THE CO_{NHA} TECHNIQUE

Although the statistical evaluation of this study is very promising, larger, progressive, and well-stratified studies are needed to establish its true value in the hierarchy

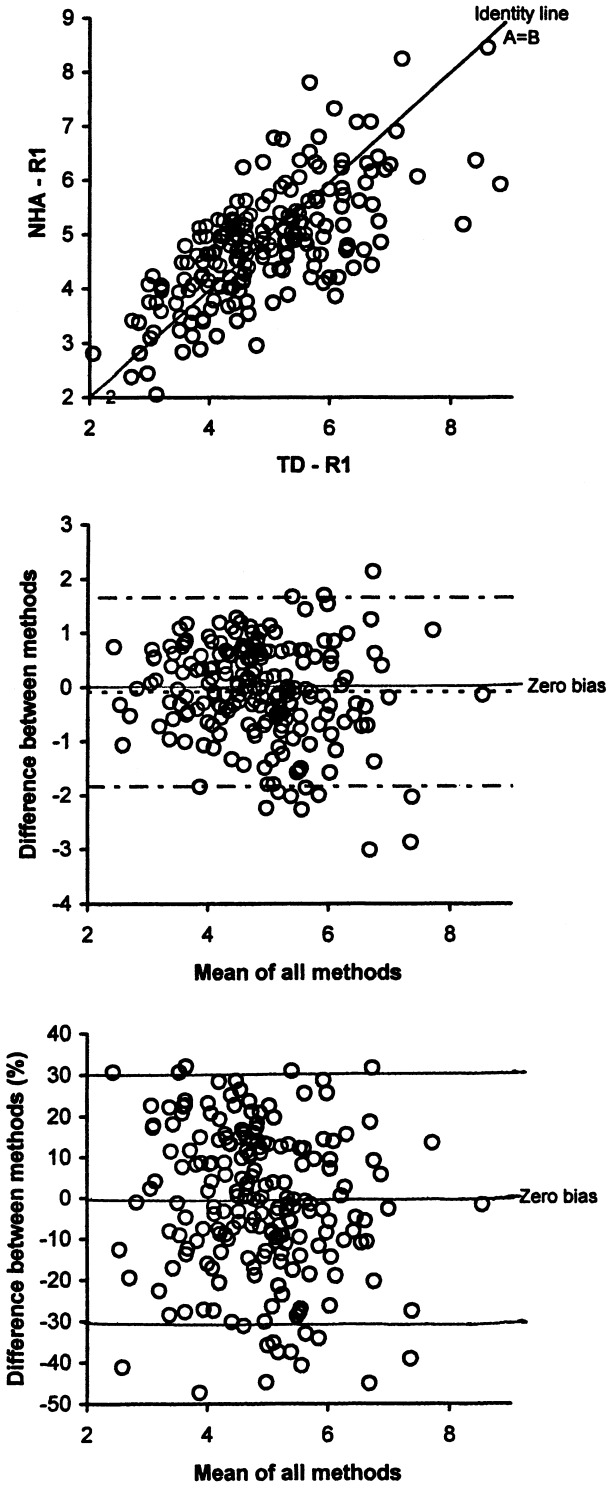

Fig. 2. Bland-Altman bias plots: CO_{TD} *versus* CO_{NHA}.

Table 5. Literature survey of Bland-Altman plot: Comparison of noninvasive CO techniques with the invasive thermodilution CO technique

Technique	Source	Year	Number of pairs	Bias (l/min)	Precision (l/min)	Agreement (l/min)
NHA		2003	203	−0.08	−0.21 to 0.04	−1.82 to 1.66
Bioimpedance						
	14	1997	2390	−0.16	± 1.16	−2.48 to 2.16
	15	1997	23	0.10	± 1.00	−1.90 to 2.10
	16	1998	35	−0.80	± 1.80	−4.90 to 3.30
Transesoph. doppler						
	17	1998	136	0.24	–	− 1.56 to 2.04
	18	2001	42	−.0.89	–	−2.67 to 0.88
	19	2003	11	−.0.98	± 0.92	−2.70 to 2.70
Partial CO_2 rebreathing						
	20	1999	14	−0.37	± 0.97	−2.20 to 1.60
	21	2002	22	−0.18	± 1.39	–
	22	2001	358	−.0.05	− 0.024 to 0.125	−1.35 to 1.46
Arterial pulse contour						
	23	2003	130	0.29	± 0.94	−1.58 to 2.16
	24	2001	490	0.32	± 1.0	−1.68 to 2.32
	25	1999	20	0.10	−0.42 to 0.55	–

of the COmethods. Our noninvasive tests, as with any other, cannot substitute for the invasive CO_{TD} technique. Because of their special technical properties, their variable clinical accuracy, and trending capability, no single noninvasive method stands out or renders the others obsolete.

There are several limitations of this approach. First, it is only applicable for adult humans over 18 years old. If arrhythmia is present, the computation will not be precise. This situation could be more prevalent at elevated heart rates over 100 beats per minute. However, this requirement (and limitation) is true for all CO measuring techniques.

The key requirement/limitation is that the measured vital signs must be measured synchronously with the corresponding $CO_{TD.}$ We are aware that CO_{TD} data was the average of three (or five) measurements, while blood pressure and heart rate were singular. Therefore, the lack of synchronization of time in obtaining the vital signs in these two comparative studies may be the source of imprecision.

There is a possibility in the future, to reduce the discrepancies of measurement time and to investigate the statistical accuracy of our method as compared with other CO measuring techniques in a progressive study, measuring the vital signs invasively and continuously. Obviously, in that case, this noninvasive technique would be tailored to an invasive approach.

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