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Accuracy of Vigileo/Flotrac monitoring system in morbidly obese patients

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ABSTRACT

Purpose: Our goal was to assess the accuracy of measuring cardiac output (CO) by the FloTrac/Vigileo (CO_V) device in comparison with thermodilution technique through pulmonary artery catheterization (PAC_{TD}) in morbidly obese patients.
Material and methods: Cardiac output in 8 morbidly obese patients was assessed twice at upright and lying position breathing ambient air. At least 4 consecutive CO measurements with 10 mL of ice-cold saline injections were performed each time. Simultaneous CO measurements were recorded with both single-bolus thermodilution and CO_V.
Results: One hundred thirty-two CO data pairs were collected. The overall mean single-bolus thermodilution 6.2 ± 1.1 L/min was lower than the overall mean CO_V 7.8 ± 1.6 L/min ($P < .001$). Lin concordance coefficient indicated that overall agreement between PAC_{TD} and CO_V was poor, 0.29. Lin concordance coefficient in sitting position was 0.29, 95% confidence interval (0.17-0.40) and in lying position was 0.30, 95% confidence interval (0.15-0.44). The Bland-Altman plot analysis showed systematically higher values from CO_V in comparison with PAC_{TD}. These differences increased in presence of high CO measurements. In 3 of 8 patients, the percentage error was lower than 20%, whereas in the other 5, it was higher than 20%. Of these 5, in 2 cases, the percentage error was greater than 50%.
Conclusion: Data obtained using CO_V vs PAC_{TD} measurements showed poor correlation. The results were not interchangeable.

1. Introduction

The global obesity epidemic [1,2] has fostered a growing interest in the surgical setting, as more of these patients require general surgery and bariatric procedures [3-5]. Because of the presence of comorbidities, the complexity of the surgery [3,6,7] and the increased incidence of perioperative complications in these patients, such as higher incidence of left and right ventricle dysfunction and subsequent higher risk of cardiac failure (11%-14%) [8] and pulmonary hypertension (5%) [9], advanced cardiovascular monitoring is required [10,11].

However, the invasiveness of classic, criterion standard cardiac output (CO) monitoring technique thermodilution by pulmonary artery catheter is not justified by improved outcomes [12,13]. For this reason, there has been an upsurge of interest in developing minimally invasive CO monitors for goal-directed fluid therapy. One such device is the FloTrac/Vigileo (CO_V) monitoring system (Edwards Lifesciences, Irvine, CA). Since its introduction in 2005 and driven by validation studies, software updates have been provided to improve the accuracy of its measurements. Previous studies have evaluated both the measurement accuracy of the device and its ability to reliably detect changes in CO or in its trend in different populations such as liver transplant and cardiac surgery, but results are contradictory [14-20]. The CO_V accuracy in morbidly obese (MO) patients has not been explored before.

Our goal was to assess the accuracy of CO measurements CO by the CO_V device (3.01 software version) in comparison with pulmonary artery catheterization (PAC_{TD}) in MO patients.

2. Materials and methods

2.1. Population

Eight MO patients (body mass index [BMI] of >35 kg/m^2 and experiencing obesity-related health conditions or BMI of >40 kg/m^2) who underwent bariatric surgery (BS) at the Hospital Clinic of Barcelona were prospectively studied. We conducted this substudy as a part of a

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more complex study addressed to investigate pulmonary gas exchange in MO patients by using a multiple inert gas elimination technique [21].

Inclusion criteria are: MO patients scheduled for BS with associated comorbidities (hypertension, diabetes mellitus, and metabolic syndrome). Exclusion criteria are: age younger than 18 years old, severe cardiovascular (ischemic cardiac disease, cardiac failure, severe heart valve disease, and rhythm disturbances) and pulmonary (chronic obstructive pulmonary disease, pulmonary hypertension, and severe asthma) diseases, and moderate or severe obstructive sleep apnea syndrome.

The study was performed according to the principles of the Declaration of Helsinki (revision of Seoul 2008), and the protocol was approved by the Ethics Research Committee of the Hospital Clinic. Written informed consent to participate in the study was obtained from each patient.

2.2. Instrumentation

This study was performed in awake, spontaneously breathing patients who had not taken any medication during the previous 24 hours. Patients underwent standard monitoring: continuous display of heart rate and pulse oximetry and noninvasive arterial pressure measurement every 5 minutes. A peripheral venous catheter was inserted in 1 hand. A 20-G arterial cannula (Arrow International, Reading, PA) was inserted, without premedication, into the radial artery under local anesthesia and was connected to a FloTrac pressure transducer (FloTrac sensor; Edwards Lifesciences) using the third-generation (3.01) FloTrac software for continuous CO display. Right internal jugular vein was cannulated under local anesthesia and ultrasound guidance. Through a venous port of 8F catheter, the PAC (Opticath catheter; Hospira, Inc, Lake Forest, IL) was inserted.

2.3. Data collection

Patients were studied within 24 hours previous to BS, placed on an electronic bed (AvantGuard 1200; Hillrom). The measurements were performed in 2 positions: sitting position at 90° and lying position at 180°. At least 4 consecutive CO measurements were performed twice in each position, with a time interval of at least 30 minutes between them. The 2 positions were permuted.

Hemodynamic parameters as heart rate, systemic blood pressure, right atrial pressure, pulmonary artery pressure, and pulmonary capillary wedge pressure were registered. Pulmonary and systemic vascular resistances (SVRs) were calculated twice at each position after CO measurements using standard formulae.

Data sets of PAC_{TD} and CO_V CO were recorded at 2 predetermined situations according to permuted positions. Zeroing of arterial pressure was performed in both positions before measuring CO. The transducer was leveled with the right atrium at each position. Simultaneous CO measurements were recorded with both single-bolus thermodilution (CO_{TD}) and CO_V. A bolus CO was calculated, as the average of 4 consecutive measurements performed randomly in the respiratory cycle over several minutes, each using 10 mL of ice-cold saline through the venous port of an 8F catheter PAC. These were compared with the CO_V displayed halfway through performing the CO measurements. The results were accepted and averaged if the following conditions were met: stable hemodynamic conditions and no arrhythmias throughout the measurements, a stable baseline temperature, a consistent shape of the thermodilution curve, and less than 15% variation between individual measurements and their average [22]. For each measurement exceeding 20% variability, an additional measurement was performed, and the 3 values closest to the mean were averaged.

In CO_V device, CO is calculated from an arterial pressure-based algorithm that uses the relationship between pulse pressure and stroke volume. The SD of the pulse pressure is determined over a 20-second window, and the arterial pulse waveform is assessed at 100 Hz. The algorithm is related to vessel compliance (influenced by sex, age, height, and weight) and peripheral resistance effects (determined from arterial waveform characteristics). The third-generation version includes 2 models for arterial tone: (1) a model that was developed predominantly from patients in normodynamic and hypodynamic conditions (as in the previous version 1.10) and (2) a model that was developed predominantly from patients in hyperdynamic conditions [23].

2.4. Statistics

Statistical description of results was performed using mean ± SD. We used the Lin concordance coefficient (LCC) and their corresponding 95% confidence intervals (CIs) [24] to assess the agreement between direct values of CO from PAC_{TD}, and CO_V devices were used The LCC measures the accuracy and precision to determine whether each data observed diverge significantly from the line of perfect concordance, that is, a lineal regression at origin (0.0) and 45° (ie, the slope of the line equals one). This value increases from 0 to 1, as the accuracy and precision of the observed data improve. The measure of agreement [25] was classified as either very poor (<0.21), poor (0.21-0.40), moderate (0.41-0.60), substantial (0.61-0.80), or almost perfect (0.81-1.00) concordance. As repeated measurements will affect the estimation of variability of the Bland and Altman confidence limits [26], a general mixed model for repeated measures, including the subject as random effect and position as fixed effects, was performed for a correct [24] estimation of bias' variability in the results. In addition, this Bland-Altman [27] graph of CO_{TD} and CO_V values was also carried out to detect consistent bias (defined as systematic mean difference between PAC_{TD} and CO_V measurements, for all range of measures), regardless of their linear correlation for 2 positions: upright and lying. This graph displays a scatterplot of the differences between measurements obtained by 2 methods plotted against the described means. Horizontal lines are drawn at the global mean difference (bias) ± 1.96 SD. We represented the Bland and Altman plot analysis with absolute values as Bland and Altman [27] described. All analyses were performed with SPSS version 18 for Windows.

3. Results

3.1. Patients characteristics

Eight MO patients (7 females/1 male; age, 52 ± 9 years; BMI, 44 ± 5 kg/m^2) were included. Four patients had hypertension, 3 from diabetes mellitus, 1 of them had dyslipidemia, and 5 were nonsmokers (8 pack years of smoking average) (Table 1).

One hundred thirty-two CO data pairs were collected. The hemodynamic parameters are represented in Table 2. In comparison with sitting position, there was a CO_{TD} increase and a SVRs decrease in the lying position.

3.2. Comparison of CO_{TD} with CO_V

The LCC indicated that overall agreement between PAC_{TD} and CO_V was poor, 0.29, 95% CI (0.20-0.39).The overall mean CO_{TD} 6.2 ± 1.1

Table 1
Demographic data of hypoxemic MO patients before BS

	MO subjects (n = 8)
Age (y)	52 ± 9
Females	7
BMI, kg/m	44 ± 5
Weight, kg	114 ± 17
Diabetes mellitus, n (%)	4 (50%)
Hypertension, n (%)	3 (38%)
Dyslipidemia, n (%)	1 (13%)

Data are expressed as mean ± SD or percentage.