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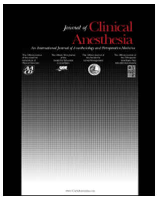

Non-invasive cardiac output monitor validation study in pediatric cardiac surgery patients

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ABSTRACT

Study objective: To validate a non-invasive cardiac output monitor in pediatric cardiac surgery patients.
Design: Prospective trial.
Setting: Operating room.
Patients: 20 pediatric cardiac surgery patients ASA physical status 3 and 4.
Interventions: Aesculon noninvasive cardiac output monitor was used and compared to the cardiac output derived from the Fick equation. Oxygen consumption was measured and blood samples were taken from the arterial line and from the superior and inferior vena cava.
Measurements: Noninvasive cardiac output and cardiac index and Fick cardiac output and cardiac index. Oxygen consumption was measured by the TreyMed metabolic monitor. Blood samples were simultaneously drawn from the arterial line and from the superior and inferior vena cava purse string sites by the surgeon, prior to commencing cardiopulmonary bypass. Another data set was obtained right after termination of cardiopulmonary bypass.
Results: There was a direct, significant relationship between Fick CO/CI and NICOM CO/CI measurements. More dispersion is detected when the magnitude of the measure increases, i.e., for older and larger patients.
Conclusions: There is a strong correlation between the cardiac output values derived from the Fick equation and the Aesculon non-invasive cardiac output monitor.

1. Purpose of study

To validate a bioimpedance non-invasive cardiac output monitor (NICOM) in pediatric cardiac surgery patients.

2. Introduction

Real-time cardiac output monitoring can be useful in the Intensive Care Unit (ICU) for monitoring critically ill patients [1]. Recent studies report that early, vigorous resuscitation of critically ill patients may lead to improved outcomes by limiting or reversing hypoxic insults that can progress to organ failure [2–5]. There are multiple modalities available for measuring cardiac output. These include carbon dioxide rebreathing methods, esophagheal doppler, thermodilution, pulse contour analysis, thoracic bioimpedance, thoracic bioreactance and methods based on the Fick principle [6]. Many are invasive and necessitate stringent fidelity to strict formulas for precise and consistent results [7–10]. In children there have been a limited number of publications on measuring cardiac output and fewer still in children with congenital heart disease [11–14]. Thoracic bioimpedance and thoracic bioreactance are methodologies that provide real-time stroke volume and cardiac output values non-invasively [15]. These methods generally involve placing Electrocardiogram (ECG) electrodes across the chest and then sending an electric current of known amplitude and frequency across the thorax. Changes in voltage are a measure of direct current resistance, also known as impedance (Z_o), across the thorax. Although this value is impacted by amount of fluid in the thorax, the instantaneous rate of the change of Z_o is believed to be related to the instantaneous flow of blood in the aorta [6]. Bioreactance devices overcome some of the limitations of bioimpedance machines by using more advanced methods and algorithms to analyze the impedance signal. The Aesculon monitoring system (Osypka Medical, Berlin, Germany and San Diego, CA, USA) is an example of such a device. We conducted a further validation study of this non-invasive cardiac output

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monitor by comparing the cardiac output (CO_{NC}) derived from the non-invasive Aesculon device to the cardiac output (CO_F) derived from the Fick principle.

3. Methods

After obtaining approval from the Western Institutional Review Board, twenty pediatric cardiac patients scheduled to undergo elective cardiac surgery in the Cardiac Operating Room were enrolled. Eight patients were <10 kg, six patients were between 10 kg and 30 kg, and six patients were >30 kg.

After induction of general anesthesia and tracheal intubation, the Treymed Metaphor metabolic monitoring system was connected to the anesthetic breathing circuit to measure oxygen consumption (VO_2). The Aesculon NICOM monitor was then applied and patient demographic data entered. Four surface EKG electrodes are placed over the skin (forehead, left side of the neck, left mid-axillary line at the level of xiphoid process and left thigh). A small, alternating electrical current flows through the thorax from the outer EKG electrodes and the resulting voltage is measured by the inner electrodes. A major contributing factor to conductance (1/impedance) of the current is blood flow in the ascending and descending aorta. The impedance to the flow of current varies according to the alignment of red blood cells in the ascending aorta. As red blood cells are aligned during systole and misaligned during diastole, there is a difference in the measured voltage during systole and diastole. This difference serves as the basis for the model that estimates the cardiac output. The mean velocity index empirically derived from a peak amplitude measurement is assumed to be an index of peak aortic acceleration of blood flow. Cardiac output derivation by Aesculon uses an algorithm which estimates stroke volume in milliliters (ml) based on the mean velocity index, the flow time and the body mass. Stroke volume multiplied by heart rate yields cardiac output in milliliters (ml) per minute.

Once median sternotomy had been performed and the aortic and venous purse strings were in place samples were drawn at two time points, immediately before commencing CPB and immediately after its termination. To determine the cardiac output via the Fick equation (Fick CO), 0.5 cm^3 blood samples were simultaneously obtained from the inferior vena cava (IVC), the superior vena cava (SVC) and the arterial line. Oxygen consumption and the cardiac output determined by the Aesculon (NICOM CO) were noted at the same time. Blood samples were analyzed by the iStat blood gas machine. Mixed venous oxygen saturation (SvO_2) was calculated by the equation $SvO_2 = 3 / 4 * SVC$ saturation $+ 1 / 4 *$ IVC saturation [16]. The Fick principle for measuring CO was determined by dividing the VO_2 by the arterio-venous oxygen content difference via the following equation:

CO_F (l/min) $= VO_2$ (l/min) / [Hb (g/dl) × 1.36 (ml O_2/g Hb) × (SaO_2 (%) $-$ SvO_2 (%))].

Hb - hemoglobin.

SaO_2 - arterial oxygen saturation (percent or %).

VO_2 - oxygen consumption (liters/minute or l/min).

Hb - hemoglobin (grams/deciliter or g/dl).

SvO_2 - mixed venous oxygen saturation (percent or %).

4. Statistical analysis

The Statistical Package for Social Sciences (SPSS 22®) was used to organize, validate and analyze the collected data. All fundamental data were examined for normality using Kolmogorov-Smirnov and Shapiro-Wilk tests. Pearson or Spearman correlation analyses, for normally and non-normally distributed data respectively, were performed to assess the strength and direction of the linear relationship between variables. Standard errors were estimated using linear regression analysis and Bland-Altman plots were used to compute bias and limits of agreement. All statistics were 2-tailed, and p values < 0.05 were considered statistically significant.

An “a priori” sample size calculation and power analysis was performed. Moreover, a post hoc power analysis was also conducted for the Fick CI and NICOM CI correlation and for the Fick CO and NICOM CO correlation.

5. Results

Twenty patients were studied generating 40 data points for comparison. The eight patients who were <10 kg had a mean weight of 5.75 kg (range 2.54–8.6) and a mean age of 0.56 years (range 0.02–0.6), the six patients who were between 10 and 30 kg had a mean weight of 16.1 kg (range 10.4–23.6) and a mean age of 5 years (range 1.8–8.2) and the six patients who weighed >30 kg had a mean weight 56.9 kg (range 50.3–63.4) and a mean age of 14.6 years (range 13.5–17.5). The surgical procedures are listed in Table 1.

The recommendation from the “a priori” estimate, assuming a correlation coefficient (r) of 0.40, was a sample size of ≈45 in order to achieve a power of 80%. A post hoc power analysis was conducted using the achieved effect size ($r = 0.46$) for the Fick CI and NICOM CI correlation. With a sample size of 40 patients, two measurements per subject, and an effect size ($r = 0.46$), we were able to achieve a power of 86%. A post hoc power analysis was conducted using the achieved effect size ($r = 0.87$) for the Fick CO and NICOM CO correlation. With a sample size of 40 and effect size achieved from the Fick CO and NICOM CO correlation analysis ($r = 0.87$), we were able to achieved a power > 95%.

There is a strong, direct and significant linear relationship between Fick CO and NICOM CO measurements, $r_s = 0.93$, $p < 0.001$. More dispersion is detected when the magnitude of the measure increases. Although less strong than between Fick CO and NICOM CO, there is a direct and significant linear relationship between Fick CI and NICOM CI measurements, $r = 0.46$, $p < 0.01$ ($p = 0.003$). Figs. 1 and 2.

The regression analysis revealed a slope ($\beta = 0.096$) related to Fick CI and NICOM CI measurements not significantly different than zero ($p = 0.63$); we could then assume that there is no proportional bias between these two methods. The *Beta* coefficient related to Fick CO and NICOM CO is larger ($\beta = -0.36$) than Fick CI and NICOM CI and it is significantly different than zero ($p < 0.001$); here we assume that there is proportional bias related to these measures, indicating that the methods do not agree equally through the range of measurements, i.e., there is more dispersion at higher CI.

The results of the Bland-Altman plots are seen in Figs. 3 and 4. The bias between NICOM CO and Fick CO scores was −0.9 with the upper and lower limits of agreement being 2.1 and −3.8 l/min respectively. The bias between the NICOM CI and the Fick CI was −0.8 with the upper and lower limits of agreement being 1.5 and −3.2 l/min respectively.

6. Discussion

Our results demonstrated a direct and significant correlation between the CO and the CI derived from the Aesculon non-invasive cardiac

Table 1
Surgical procedures.

Surgical procedures	
Atrial septal defect repair	6
Ventricular septal defect repair	6
Tetralogy of fallot repair	2
Bidirectional cavopulmonary anastomosis	1
Fontan	1
Right ventricular outflow tract reconstruction	1
Mitral valvuloplasty	1
Aortic arch reconstruction	1
Repair of anomalous left coronary artery from the pulmonary artery	1
Total	20