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ORIGINAL ARTICLE

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Inaccuracy of a continuous arterial pressure waveform monitor when used for congenital cardiac catheterization

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Abstract

Objective: To determine the accuracy of a continuous cardiac output monitor (FloTrac sensor) for measuring cardiac index in children with congenital heart disease undergoing cardiac catheterization. Cardiac index is a critical hemodynamic parameter measured during catheterizations in children with congenital heart disease. This has been challenging to measure accurately and many clinicians rely on predictive equations for calculating cardiac index.

Design: Prospective, nonrandomized trial.

Setting: Tertiary care congenital heart center.

Patients: Consecutive participants ≤18 years old undergoing clinically indicated cardiac catheterizations from September 2014 through August 2015.

Interventions: Oxygen consumption was measured using the Vmax Encore 229 monitor attached to the ventilator circuit. The FloTrac transducer with third generation software was connected to a pigtail catheter in the descending aorta and cardiac index was obtained.

Outcome Measures: Cardiac index by the Fick equation using measured oxygen consumption was compared to cardiac index from the FloTrac sensor using paired *t*-test and Bland–Altman analysis.

Results: 39 participants (median age 5.1 years, 1.5-18.3, 64% female) were studied. Cardiac index by FloTrac was higher than cardiac index by Fick (6.4 ± 3.4 vs 3.7 ± 1.2 L/min/m^2, $P < .001$). Bland–Altman analysis showed a consistent overestimation of cardiac index by FloTrac which worsened as cardiac index increased (mean bias 2.7 L/min/m^2, 95% limits of agreement −4.2, 9.5).

Conclusions: The results of this study show that the FloTrac sensor provides cardiac index measures which are not accurate enough to justify use in children with congenital heart disease undergoing catheterization. Further studies may allow for modifications of the algorithms to obtain more accurate cardiac index in this population.

KEYWORDS
catheterization, congenital heart disease, diagnostic, hemodynamics, pediatrics

1 | INTRODUCTION

Cardiac index (CI) is vital for hemodynamic calculations in cardiac catheterizations for congenital heart disease (CHD). Oxygen consumption (VO_2), used in the gold standard Fick equation[1,2] to calculate CI in patients with intracardiac shunts, is cumbersome to measure. Many catheterization labs rely on published predictive equations for VO_2, such as those by LaFarge or Lundell,[2,3] which are known to be suboptimal.[4–9] The FloTrac sensor (Edwards Lifesciences Corp., Irvine, CA) and Vigileo Monitor (Edwards Lifesciences Corp.) connect to standard arterial catheters and use arterial waveform tracings to continuously calculate CI,[10–13] but have not been used in children with CHD undergoing cardiac catheterization. The purpose of this study was to assess the accuracy of the FloTrac sensor and Vigileo Monitor for use in the hemodynamic evaluation of children with CHD during cardiac catheterizations.

2 | METHODS

After approval from the University of Arizona Institutional Review Board, consecutive participants ≤18 years old undergoing clinically indicated catheterizations were prospectively approached for enrollment from September 2014 through August 2015. Due to technical limitations of VO_2 measurement technology, participants were excluded from this study if they had <50 mL tidal volume, >10% difference in inspiratory and expiratory tidal volumes, fractional inspired oxygen concentration >60%, presence of a chest tube for air leak, clinical deterioration during VO_2 measurement, failure to achieve steady state during VO_2 measurement or refused to consent to participate in the study. All catheterizations were performed under general endotracheal anesthesia using sevoflurane; one patient received propofol because of a previous episode of malignant hyperthermia. VO_2 was measured using the Vmax Encore 229 metabolic cart with the Pulmonary Function and CardioPulmonary Exercise Measurement Module (Carefusion, Loma Linda, CA). VO_2 measurements were recorded after at least a 15 min steady state period. Steady state was defined as a period of at least 5 min with <10% fluctuation in values for oxygen consumption and carbon dioxide production. Flow sensor and gas calibration for VO_2 measurements were performed according to the manufacturer's instructions prior to each catheterization. The flow sensor was connected to the expiratory limb of the ventilator circuit and all expired gas returned to the anesthesia ventilator for appropriate scavenging of inhaled anesthetic. During the catheterization, prior to angiography and while in a steady hemodynamic state, the FloTrac transducer with third generation software was connected to a 4- or 5-Fr pigtail catheter, as appropriate for patient size (<20 kg or ≥20 kg), in the descending aorta and CI was obtained over 5 min with simultaneous VO_2 measurement. CI by the Fick equation using measured VO_2 was compared to CI from the FloTrac sensor using paired *t*-test and Bland–Altman analysis for accuracy.[14] A priori power analysis revealed that a sample size of 50 would allow for detection of a 20% difference between the two methods of measuring CI with a power of 0.80 and alpha of 0.05. To assess for the possible contribution of intracardiac shunting to measurement differences between the FloTrac and Fick CI, subgroup analyses were performed for participants with left to right shunts (atrial septal defect, ventricular septal defect, patent ductus arteriosus, or surgical aorto-pulmonary shunt) and those without shunts. Comparisons were made with paired *t*-tests and Bland–Altman analysis for accuracy.

3 | RESULTS

Fifty-three participants were approached for enrollment, with 39 (median age 5.1 years, range 1.5–18.3; 64% female) with complete data comprising the final data set (Figure 1). Indications for catheterization are shown in the Table 1. There were no adverse events or procedural complication related to the use of the FloTrac. CI by FloTrac was higher than CI by Fick (6.4 ± 3.4 vs 3.7 ± 1.2 L/min/m^2, $P < .001$). CI by FloTrac correlated poorly with CI by Fick ($R^2 = 0.035$, Figure 2). Bland–Altman analysis (Figure 3) showed a consistent overestimation of CI by FloTrac which worsened as CI increased (mean bias 2.7 L/min/m^2, 95% limits of agreement −4.2, 9.5). Despite not achieving the intended enrollment based on a priori power analysis, post hoc power analysis revealed that these findings had a power of 1.0 with an alpha of 0.05 to detect a difference >20% between the methods of measuring CI.

For the subgroup analyses, there were 24 participants in the left to right shunt group and 15 without shunts. In the shunt group, CI by FloTrac was higher than CI by Fick (6.8 ± 3.9 vs 3.8 ± 1.2 L/min/m^2, $P = .002$). Bland–Altman analysis showed a consistent overestimation of CI by FloTrac (mean bias 3.0 L/min/m^2, 95% limits of

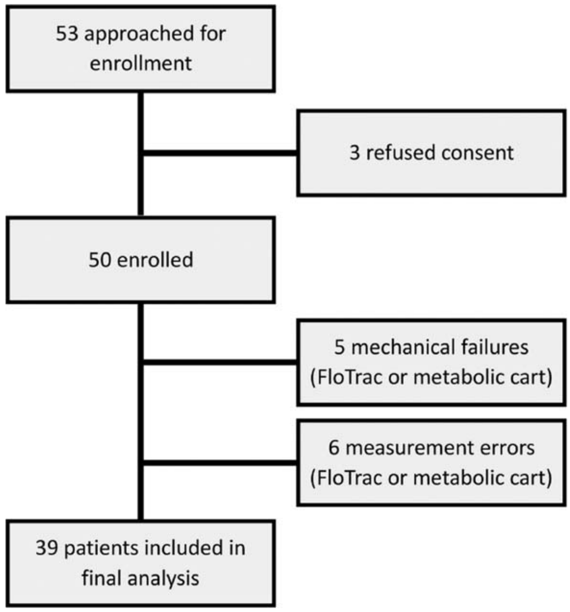

FIGURE 1 Enrollment flow diagram

TABLE 1 Indications for cardiac catheterization

Indication for catheterization	N (%)
ASD (one with concurrent pulmonary valvuloplasty)	12 (31)
PDA	7 (18)
Diagnostic/shunt quantification	7 (18)
Pulmonary artery/RV-PA conduit intervention	4 (10)
Aortic coarctation	3 (8)
Pre-Fontan hemodynamic evaluation	2 (5)
Post-Fontan hemodynamic evaluation	2 (5)
IVC obstruction	1 (3)
Post-transplant evaluation	1 (3)

Abbreviations: ASD, atrial septal defect; IVC, inferior vena cava; PDA, patent ductus arteriosus; RV-PA, right ventricle to pulmonary artery.

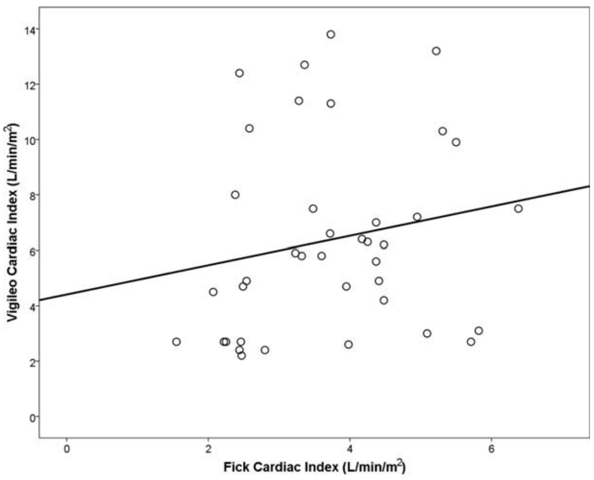

FIGURE 2 Correlation scatterplot comparing cardiac index by Fick to cardiac index by FloTrac sensor/Vigileo (Vigileo). There is poor correlation between the measures ($R^2 = 0.035$)

agreement −5.2, 11.1). In the group without shunt, CI by FloTrac was higher than CI by Fick (5.7 ± 2.6 vs 3.5 ± 1.3 L/min/m^2, $P = .001$). Bland–Altman analysis showed slightly better agreement, but still an overestimation of CI by FloTrac (mean bias 2.2 L/min/m^2, 95% limits of agreement −2, 6.4).

4 | DISCUSSION

In this prospective study of children ≤18 years with a variety of congenital heart defects undergoing cardiac catheterization, the FloTrac sensor with third generation software was found to consistently overestimate CI. Given this discrepancy, the current technology would not be adequate to safely replace Fick calculation of CI using a directly measured VO_2 in this population during cardiac catheterizations.

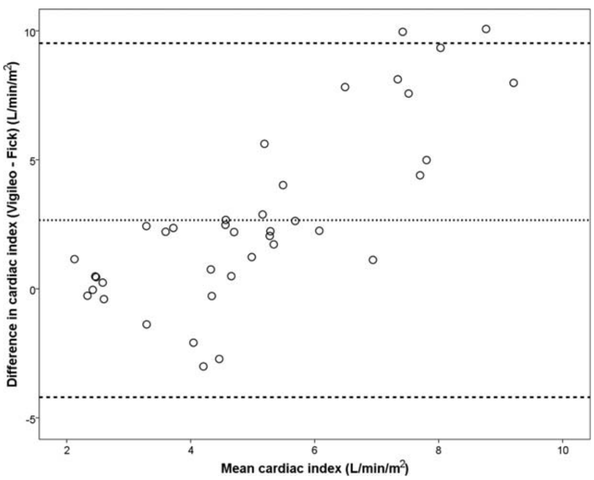

FIGURE 3 Bland–Altman analysis for cardiac index from measured oxygen consumption (Fick) compared to cardiac index from the FloTrac sensor/Vigileo monitor (Vigileo). There is a significant overestimation of CI as measured by the FloTrac which worsens as CI increases

The FloTrac algorithms for translating an arterial pressure waveform into CI are based on the arterial compliance and systemic vascular resistance as well as variation due to age, gender and body surface area in adults.[15] Given that most adults have higher systemic blood pressure and some degree of increased arterial stiffness relative to children, it is not surprising that we identified variation between the FloTrac and Fick CI in the study population. In addition, it is suggested from our data that patients with a CI by Fick ≤5 L/min/m^2 may have had more accurate CI by FloTrac (Figure 3) which may have to do with the normal expected range of CI in adult patients and limitations in the FloTrac algorithms when these are exceeded. Several studies have also shown the FloTrac to be less accurate in clinical settings with decreased systemic vascular resistance,[16,17] which is likely analogous to pediatric patients. In addition, flow distribution in children is different than in adults, with a higher degree of cerebral flow compared to systemic flow which decreases with age.[18] Children with CHD may have other vascular factors, such as aorto-pulmonary shunts or collateral arteries that could lower systemic vascular resistance and alter the arterial pulse waveform in ways that cannot be accounted for with the current FloTrac technology. This could explain why participants in this study with left to right shunts had less accurate FloTrac measures compared to those without shunts. With each successive generation of FloTrac, there has been improvement in the CI generated as data from more patients are incorporated into the algorithms.[19–22] This has still only included adult patients, so factors found in younger patients, particularly those with CHD, have yet to be accounted for and incorporated into the algorithms.

Anecdotally in our study, all 3 participants with aortic coarctation demonstrated a marked difference in arterial waveforms proximal and distal to the obstruction, as expected. This led to the FloTrac CI being significantly lower when measured distal to the obstruction, but there were not enough data points to perform robust statistical analysis on this group. In addition, we attempted to measure pulmonary flow by attaching the FloTrac to a balloon wedge catheter in the pulmonary artery in the first participant, but the pressure was too low for the FloTrac to accept and CI could not be calculated. Further attempts to measure pulmonary flow were abandoned for this study.

While the third generation of the FloTrac software is not acceptable for use in children with CHD undergoing cardiac catheterization, this technology could prove to be vitally important for this patient population. Currently, the technology is designed to measure systemic CI, but pulmonary flow and pulmonary vascular resistance are often more important during congenital catheterizations to guide therapy.[23] Future refinements in the technology that could allow for accurate, real-time flow quantification in individual pulmonary arteries would help guide interventions and immediately assess their efficacy. An even more interesting application would be measures of flow in the pulmonary circuit of Fontan participants. One of the major challenges in the management of patients with Fontan physiology is determining their pulmonary vascular resistance, and the current method of using Fick CI is likely inaccurate due to the nonpulsatile nature of the flow[23]; it is unclear if the current FloTrac technology could be adapted to continuous, low velocity venous flow.

Our findings were limited by several factors. First, this was a small series from a single center, so the results may not be broadly generalizable, but the wide variety of congenital defects present in the participants may ameliorate this. Second, the Vmax Encore 229 monitor could not measure VO_2 in children <10 kg as their tidal volume was insufficient for the machine to measure, so we could not provide data on the accuracy of the FloTrac for the smallest participants, but it is hard to think that it would be any better than the other participants. The intent of this study was to determine an accurate CI at a specific instance during a cardiac catheterization, and while the FloTrac sensor was inaccurate in this setting, it may be valuable as a tool to measure trends in CI for patients in the intensive care unit, however, this study was not designed to assess this as repeated measures of CI by Fick and FloTrac were not performed during individual catheterizations.

In conclusion, the results of this prospective study show that the FloTrac sensor with third generation software cannot be used to reliably measure CI in children with CHD undergoing catheterization. Further studies may allow for modification of the algorithms to obtain more accurate CI in this population which could provide clinically important data for many patients with CHD, particularly those with single ventricle physiology.

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CONFLICT OF INTEREST

The authors have no relationships with industry to declare.

AUTHOR CONTRIBUTIONS

The funders had no role in the design and conduct of the study, in the collection, analysis, and interpretation of the data, or in the preparation, review, or approval of the manuscript.

Study design: Seckeler, Higgins
Data analysis: Seckeler
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