The Value of Noninvasive Continuous Cardiac Output Monitoring in Assessment of Hemodynamic Status in Critically Ill Children

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Abstract- Access to reliable, rapid, and continuous hemodynamic monitoring parameters is essential for early diagnosis and prompt treatment of hemodynamic disorders in critically ill children. The aim of this observational study was to compare the accuracy of continuous non-invasive cardiac output monitoring (NICCOMO) device data with transthoracic echocardiography (TTE) and inferior vena cava (IVC) ultrasound findings in assessing cardiac output (C.I), circulatory fluid adequacy, and finally Determination of hemodynamic status in patients with Critical conditions hospitalized in the Pediatric Intensive Care Unit (PICU). In this observational study, forty-four critically ill children that were admitted to PICU were evaluated. We used NICCOMO, TTE, and IVC ultrasonography at the same time in critical patients. The association between NICCOMO parameters and echocardiogram cardiac index and IVC quality in ultrasound is compared. The agreement between CI measured by TTE and NICCOMO was assessed using the Bland-Altman analysis method. NICCOMO is not a reliable instrument for determining CI in children with an unstable hemodynamic status. However, the parameters of this device are reliable in assessing the patient's hemodynamic status. Findings showed that 90% of patients in the normal hemodynamic state in NICCOMO have SVR. I in the normal range (P<0.001), and all cases in hypervolemic state had volume overload IVC in ultrasonography analysis. Noninvasive continuous cardiac output monitoring could be used to estimate unstable patients' hemodynamic status in the initial stages for making timely treatment-related decisions, but its use for accurate cardiac index measurement is not reliable in all cases.

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Introduction

Critically ill patients have unstable hemodynamic status, and they are at risk of organ dysfunction. Early recognition and prevention of inadequate tissue perfusion and oxygenation and development of shock or organ injury is the cornerstone of critical care.

Determining adequate oxygenation and perfusion of vital organs of the body is often based on physical examination and interpretation of standard hemodynamic or laboratory parameters. The main challenge in the early detection of septic shock in children is the lack of "gold standard" criteria for shock diagnosis. Most of the suggested measures in pediatric shock resuscitation care include the selection of the type and volume of fluids and vasoactive drugs based on expert opinion, data from studies in adults, and uncontrolled studies in children. The optimal marker for shock identification and response to resuscitation therapies is still controversial, and whether laboratory markers or other available hemodynamic or metabolic assessments improve shock resuscitation in children is still unclear (1).

The hemodynamic response to resuscitation in children appears to be varied and different from that in

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adults. Unlike adults, cardiac output and low systemic vascular resistance (SVR) are lower in children and are associated with increased mortality in children with septic shock and have been shown to achieve the therapeutic goal of cardiac index (CI): 3.3-6.0 L/min/m2 improves survival in children's shock (2).

Most current instructions for prescribing fluids to children are based on previous patients' experiences or the use of vital signs as a response to treatment, and it is overlooked that in children with critical conditions, the response to treatment varies from patient to patient (3).

Therefore, reliable hemodynamic monitoring parameters are needed to reflect cardiac output measurement, blood flow, systemic vascular resistance, and indicator of fluid overload to reflect fluid responsiveness and intravascular fluid status.

CVP has been traditionally used to guide fluid therapy and is considered to determine right atrium preload. The value of CVP is affected by the diastolic compliance of the right ventricle (R.V), intra-abdominal pressure, and positive end-expiratory pressure. CVP is an inadequate marker of left ventricular preload and cannot predict fluid response or fluid overload, and is often poorly correlated with cardiac output in children (4-6).

CVP is an invasive procedure and has several complications such as arrhythmia, chamber injury, vascular or nerve damage, pneumothorax, hemothorax, increased risk of infection, thrombosis and embolism. In addition to the above, it has disadvantages such as prolonged hospital stay, increased health care costs, and reduced quality of life. As a result, the use of this method in children is very limited (7).

The recent update of the American College of Critical Care Medicine (ACCM) and the latest guidelines for the management of pediatric septic shock emphasize on use of cardiac output (C.O), cardiac index (CI), and SVR index. In contrast, some authorities advise measuring C.O only at the end of the algorithm, after fluid and vasoactive agents are administered (2,8).

It is noteworthy that excessive fluid resuscitation and positive fluid balance are associated with multiple organ failures such as deteriorating renal function, acute respiratory distress syndrome, prolonged ICU stays, and increased risk of disease and mortality (9,10).

Classically, C.O monitoring had been performed via PAC thermodilution, which is not only technically difficult in children but also has a significant risk of complications. As a result, the use of this method in children is very limited (11).

Functional echocardiography has the ability to provide real-time assessment of cardiac function and is the gold standard for assessing patient hemodynamics and deciding on targeted treatment in critical infants and children, thus improving patient care. Echocardiography has certain limitations, the most important of which is the need for skilled people to do it, and sometimes obtaining high-quality images to accurately assess the performance of a child with mechanical ventilation can be challenging (12).

According to one study, ultrasound of the inferior vena cava (IVC) is a good criterion for assessing fluid status in children with shock. The results showed that there is a significant relationship between IVC diameter and measured CVP values in the same patients (13).

As a result, over the last decade, there has been increasing use of noninvasive C.O monitoring modalities. The ideal monitor should be noninvasive, without side effects, valid, reliable, operator independent, easy to use, continuous and cost-effective.

The aim of this article was to validate the parameters of noninvasive continuous cardiac output monitoring (NICCOMO) for the prediction of cardiac function and fluid condition in children with unstable hemodynamic status.

Materials and Methods

This observational project was approved and registered by the research ethics committee at the Children's Medical Center of Tehran University Medical science (IR.TUMS.CHMC.REC.1397.109). The study was performed at PICU in Tehran Children's Medical Center, which is excellent academic tertiary care from July 2020 to December 2020. This center is the referral center for critically ill children in the country. Because the study was time-limited, all patients admitted to the PICU were included in the study if they met the inclusion criteria, and their parents registered their written consent.

In the present study, three non-invasive hemodynamic control methods, including NICCOMO, T.T.E, and IVC ultrasound, were used simultaneously to determine the hemodynamic status of critically ill patients; finally, the relationship between NICCOMO parameters and cardiac echocardiography index and IVC quality in ultrasound is compared.

Inclusion criteria are based on organ dysfunction criteria, including cardiovascular and respiratory systems (14). Inclusion and exclusion criteria are listed (Table 1).

Table 1. Inclusion and exclusion criteria

○ **Inclusion Criteria**: any of A or B :

A- Cardiovascular dysfunction:

Despite administration of isotonic intravenous fluid bolus ≥60 mL/kg in 1 hr:
decrease in BP (hypotension) systolic BP <90 mm Hg, mean arterial pressure <70 mm Hg, <5th percentile for age, or systolic BP <2 SD below normal for age

or

Need for vasoactive drug to maintain BP in normal range (dopamine >5 μg/kg/min or dobutamine, epinephrine, or norepinephrine at any dose)

or

Two of the following:

- Unexplained metabolic acidosis: base deficit >5.0 mEq/L
- Increased arterial lactate: >1 mmol/L or >2× upper limit of normal
- Oliguria: urine output <0.5 mL/kg/hr
- Prolonged capillary refill: >5 sec
- Core-to-peripheral temperature gap: >3° C (5.4° F)

B- Respiratory dysfunction :

PaO 2 /FIO 2 ratio <300 in absence of cyanotic heart disease or preexisting lung disease
or
PaCO 2 >65 torr or 20 mm Hg over baseline PaCO 2
or
Need for >50% FIO 2 to maintain saturation ≥92%
or
Need for nonelective invasive or noninvasive mechanical ventilation

○ **Exclusion Criteria :** any of this criteria**:**

1- Weight<3.5 kg
2- Weight>30 kg
3- Chest wall edema or tense ascites
4- On mechanical ventilator with PEEP>7
5- Massive bilateral plural effusion
6- Cardiac arrhythmias
7- Non repaired Congenital heart disease

BP, Blood pressure; FIO 2 , fraction of inspired oxygen;
; PaCO 2 , arterial partial pressure of carbon dioxide; PaO 2, partial pressure arterial oxygen; SD, standard deviations

NICCOMO

NICCOMO Check spelling Gmbh, Germany) using 4 skin electrodes (sensor), based on transthoracic bioimpedance, applies an electrical current of known amplitude and frequency across the thorax. Changes in voltage over the circuit are caused by charges impedance of tissue electrical conductivity. The bio-impedance is the electrical resistance of the thorax to this current. The changes are used to calculate hemodynamic parameters. In addition to the vital signs of standard monitoring, the device also provides information on 23 other parameters. Hemodynamic parameters obtained from these machines were categorized into four groups: Flow, Resistance, Fluid, and heart contractility variables.

Also, NICCOMO, with the combination of impedance waves, demonstrated patient hemodynamic status on the multi parameters graph in 9 areas (Figure 1).

We decided to analyze the following parameters from the device data:

CI, systemic vascular resistance index (S.V.R.I), thoracic fluid content index (T.F.C.I) and device graph.

Body surface area (BSA)=calculated with machine by weight and Height.

Cardiac index=cardiac output (C.O)/ BSA (l/min/m2)

Systemic vascular resistance (SVR) index = SVR/ BSA (dyn.sec.cm-5 m2)

Thoracic fluid content (TFC): the electrical conductivity of the chest which is determined by the presence of intravascular and extra vascular fluids

Thoracic fluid content index (T.F.C.I)=TFC/ BSA (/k ohms/m2)

SVR.I values by NICCOMO was compared with the normal ranges of SVR.I measured using the ultrasonic cardiac output monitor (USCOM) according to age (14). The data in comparing to normal range of USCOM were subdivided in three categories including more than normal, less than normal and normal ranges. Then we evaluated the association of SVR.I category with vasoconstriction and normal hemodynamic state in NICCOMO graph (5 and 7 areas).

The normal range and S.D of TFC and TFC.I in children is unknown. Therefore, difference TFC.I was compared between hypervolemic and normal hemodynamic state in NICCOMO graph. (5 and 9 areas)

Trans thoracic echocardiography (T.T.E)

Trance thoracic Echocardiography examinations were measured by a single specialist who was blinded to all values measured by other instruments.

2D echocardiography machine (Philips, AffinityCX50) and (S-8-3) MHz phased array (cardiac) transducer was performed to measure cardiac output.

Left ventricular outflow tract (LVOT) diameter was recorded using the parasternal lung axis view in two dimensions. In each study, a five-apical chamber was obtained, a pulse wave gate 1 cm close to the aortic valve, and an integral velocity time (VTI) time of 3-5 respiratory cycles was recorded. Mean VTI was used to calculate CI. Calculations are based on the American society of echocardiography guidelines (15,16).

Stroke volume (S.V)=VTI×LVOT area

C.O=S.V×H.R

CI=C.O/BSA

Inferior vena cava ultrasound

IVC is the largest low-pressure vein in the body. The size and collapsibility of the IVC reflects venous pressure due to intravascular volume changes. Therefore, IVC diameter is the important diagnostic evaluation of hypovolemia or volume overload state.

Assessment of the IVC collapsibility (compressibility) was done by ultrasound machine (affinityCX50) with an S-8-3MHz phased array or C2-4 curvilinear transducer. A subcostal long axis view of the IVC obtained the IVC and right atrial (R.A) junction and confluence of the hepatic vein. IVC diameter was measured at the level of the hepatic vein at the end of inspiration and end-expiration (3).

The lower collapsibility indices denote volume depletion, and low venous contractility indicates fluid overload.

We categorized IVC collapsibility into 5 quality groups:

1-Narrow IVC, collapse

2-NarrowIVC, collapse with inspiration

3-Dilated IVC, little or no collapse with inspiration

4-Dilated IVC, minimal collapse

5-NormalIVC, with change in inspiration & expiration

Groups 1 and 2 indicate a lack of circulating fluids, Groups 3 and 4 show the state of volume overload, and Group 5 represents the normal hemodynamic status.

Statistical analysis

Statistical analysis was carried out using IBM SPSS statistical version 23. The concordance between CI from TTE and NICCOMO was evaluated using by Bland-Altman method and TTE as the gold standard. We used the chi-square test to compare SVR. I range and IVC quality group between different NICCOMO graph groups. Kruskal-Wallis test was used to determine the difference in TFC. I between NICCOMO graph groups in this study *P* of <0.05 was considered significant.

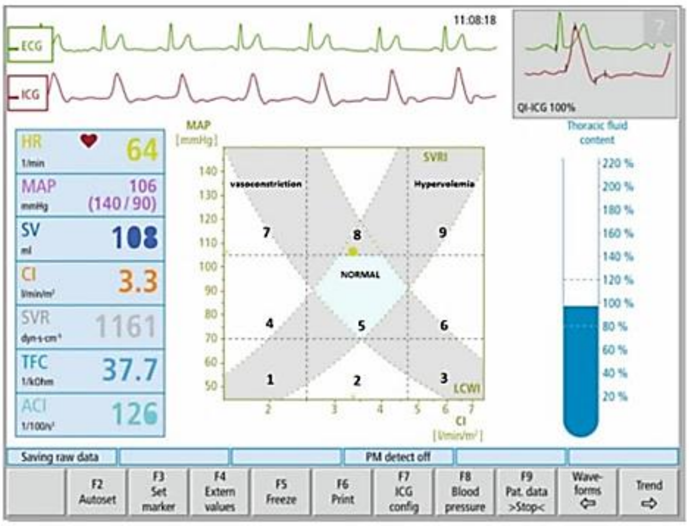

Figure 1. Niccomo multi parameters graph

Results

Forty-four children were enrolled for the study with demographic characteristics including 22 boys (50%), 22 girls (50%), Age: 2-48 month (13.1±12.4), Weight: 3.5-20 kg (8.3±3.3), BSA: 0.2-0.75 (0.39±0.12), height:54-104 (70±13.6). The agreement between C. I measured by TTE, and NICCOMO was assessed using the Bland-Altman analysis method. The difference between TTE and NICCOMO is plotted against the average of the two estimates for each parameter (Figure 2). The mean difference of 1.96 SD (the lower and upper limit was -0.8 and +0. 5 L/min//m2. The result of pitman's test showed that there are significant (r=0.6) differences between the measuring errors of the two methods.

Hemodynamic status in NICCOMO graph compared with TFC.I, SVR. I categories and IVC quality groups (Table 2). 90% of patients in normal hemodynamic state (area 5 in the graph) had SVR. I in the normal range (P<0.001). Mean T.F.C.I values in 9 areas of the NICCOMO diagram were shown (Table 3). There was a significant difference between the amounts of TFC. I in different areas (P=0.007). Results of IVC by ultrasonography analysis showed all cases in the hypervolemic state in NICCOMO (area 9) have volume overload IVC in ultrasonography assessment (group 3 or 4). In 8 cases of 10 subjects in the normal hemodynamic state (graph 5 in NICCOMO graph) have normal IVC collapsibility (group 5), (P=0.049).

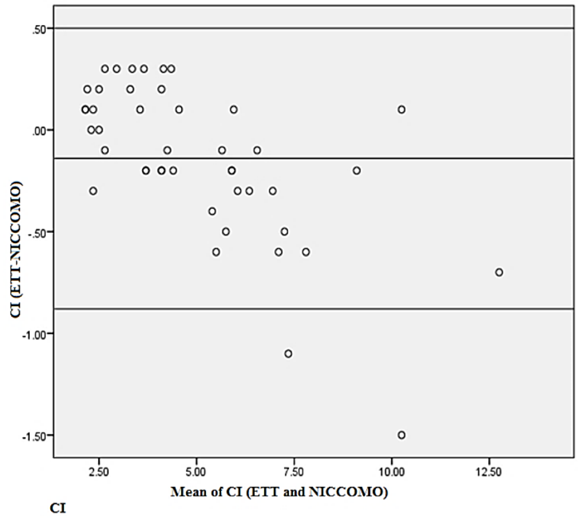

Figure 2. Bland_altman analysis

Table 2. Frequency of parameters

Parameters	Frequency	Percentage (%)
NICCOMO Diagram area 1	8	18.2
NICCOMO Diagram area 2	1	2.3
NICCOMO Diagram area 3	1	2.3
NICCOMO Diagram area 4	4	9.1
NICCOMO Diagram area 5	10	22.7
NICCOMO Diagram area 6	2	4.5
NICCOMO Diagram area 7	9	20.5
NICCOMO Diagram area 8	3	6.8
NICCOMO Diagram area 9	6	13.6
SONOGRAPHY IVC group 1	6	13.6
SONOGRAPHY IVC group 2	5	11.4
SONOGRAPHY IVC group 3	5	11.4
SONOGRAPHY IVC group 4	6	13.6
SONOGRAPHY IVC group 5	22	50
SVR.I normal range	29	65.9
SVR.I less than normal range	5	11.4
SVR.I more than normal range	10	22.7

Table 3. Mean TFC.I based on NICCOMO areas

Niccomo diagram area	Number	Mean TFC.I
1	8	22.38
2	1	27.00
3	1	26.00
4	4	14.50
5	10	24.40
6	2	20.50
7	9	16.22
8	3	7.33
9	6	41.17

Discussion

To the best of our knowledge, this study was the first research to simultaneously assess the hemodynamic status of critically ill children with unstable conditions through three non-invasive procedures, TTE, IVC, and impedance cardiography (ICG) (through the NICCOMO device). However, one study compared three non-invasive methods alternately in pediatric intensive care settings in patients with stable hemodynamic (17), and in another study, children with a diagnosis of sepsis regardless of hemodynamic status were routinely evaluated using three methods: echocardiography, lung ultrasound, and IVC ultrasound before receiving fluid, and concluded that this method allows the benefits and the risks of fluid resuscitation should be assessed for each patient (3).

Also, the current study compared the ICG results with those of the other two procedures under investigation. More specifically, the objectives of the study were twofold: (a) to evaluate the reliability of the CI parameter of the NICCOMO device in comparison to the same parameter as measured through the TTE procedure; and (b) to confirm the diagnosis modes of normal condition, vasoconstriction, and hypervolemia in the output graph produced by the NICCOMO device, in comparison to the IVC index, and the T.F.C.I and S.V.R.I values.

In several studies, the CI measure calculated through the ICG procedure examining adults was reported as reliable (18-22).

However, in another study, there was a weak correlation and discrepancy between the absolute CI values measured by ICG and trans-thoracic Doppler echocardiography in healthy resting volunteers (23).

In the case of healthy females in late pregnancy, there was a poor agreement between the stroke volume and cardiac output data produced by ICG and TTE, and their association was moderate under best conditions; meanwhile, the ICG measures were greater than those of TTE (24).

In addition, in assessing left ventricular systolic function in adults, there was no association between output fraction in TTE and left ventricular systolic function parameters in ICG (25). Validation studies in experimental animal and human neonatal models should be performed prior to routine clinical use (26).

In one study, CI measured by bioreactance in young children differed from the expected range for patients' age and weight, and in a large percentage of measurements less than normal, although not compared to other instruments (27).

In the present investigation, the CI parameter observed was compared according to the TTE and NICCOMO methods; while a poor degree of agreement was found between the data, the ICG procedure showed a higher measure. As it seems, NICCOMO is not a reliable instrument for determining CI in children with an unstable hemodynamic status. In the graph generated by NICCOMO, a patient’s normal condition, vasoconstriction, or hypervolemia is displayed based on the results of the measurement parameters. In the case of the patients diagnosed with a hypervolemia condition, the results of the IVC quality were probed, and it was revealed that there was a strong agreement and association between the data of the two methods. Moreover, the TFCI values in such patients were significantly greater than those of other patients at the hospital; as a result, the NICCOMO diagnostic capacity in the case of hypervolemia was reliable.

In the present study, the SVRI values resulting from NICCOMO were compared to the normal range of the parameters, which were modified according to each patient’s age, and it was revealed that in the case of vasoconstriction, the NICCOMO graph showed SVRI values greater than normal values; in contrast, for the patients with a normal hemodynamic status, the SVRI values were normal. Therefore, the NICCOMO estimation of vasoconstriction appeared to be reliable.

Considering the fact that the graph produced by NICCOMO is a result of such parameters as mean arterial pressure, cardiac index, TFCI, and SVRI, it could be concluded that the difference between the CI and TTE results would not have a substantial impact on the final estimation of a patient’s hemodynamic status.

ICG is a fast and non-invasive procedure; it does not require experience and specialists to operate it (as opposed to IVC and TTE), and it could be used to estimate unstable patients’ hemodynamic status in the initial stages for the sake of making timely treatment-related decisions, but its use for accurate cardiac index measurement is not reliable in all cases.

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