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Electrical cardiometry compared to transesophageal doppler for hemodynamics monitoring and fluid management in pediatrics undergoing Kasai operation. A randomized controlled trial

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Keypoints

Infants with biliary atresia undergo hepatoportoenterostomy (Kasai procedure) commonly without cardiac output (CO) monitoring. A central venous pressure (CVP) catheter is used to guide fluids. Inserting a Pulmonary artery floating catheter for the purpose of measuring CO for this young age can be associated with complications. In this article non-invasive Electrical bioimpedance cardiometry (EC) and the minimally invasive transoesophageal Doppler (TED) methods were able to add an additional facility to monitor continuously the CO and guide fluid management with minimal risks.

Abstract

Introduction

Infants suffering from biliary atresia commonly undergo hepatoportoenterostomy (Kasai procedure) without cardiac output (CO) monitoring and with only a central venous pressure (CVP) catheter to guide fluid requirements. Aim is to evaluate non-invasive electrical bioimpedance cardiometry (EC) compared to minimally invasive transoesophageal Doppler (TED) for CO monitoring and fluid management and relationship with CVP.

Material and methods

A prospective randomized controlled study. 42 infants: TED (*n*=21), and EC (*n*=21). Intravenous fluids were guided by stroke volume variation (SVV) (%) of EC and corrected flow time (FTc) (msec) of TED with CVP monitored in all.

Results

Median [Interquartile] age (74 [58-86] vs. 73 [62-80] days, p=0.56), weight, (5.0 [4.2-5.2] vs. 5.0 [5.0-5.5] kg, p=0.11), operative time 6[5-6] vs. 6[5-6] hours (h) p=0.47) and crystalloids intake (300[275-330] vs. 300[270-336] ml, p=0.59) in EC and TED respectively. EC CO was constantly higher than TED CO (l/min) 0.95[0.87-1.2] vs. 0.9[0.7-1.1] p=0.001 and 1.02[0.87-1.31] vs. 0.8[0.7-1.25], p=0.001, post-induction and mid-surgery respectively. A good degree of reliability between TED and EC CO: post-induction, (Intra-class correlation (ICC) =0.693, p<0.001), 1st h (ICC=0.744, p<0.001), 2nd h (ICC=0.739, p<0.001), 3rd h (ICC=0.769, p<0.001) and 4th h (ICC= 0.617, p=0.002). Bland and Altman analysis of CO (l/min) between EC and TED showed reasonable bias [mean] but broad limits of agreement (± 2 SD): Post-induction: 0.122 (0.636 to -0.391), 1st h 1: 0.147 (0.605 to -0.310), 2nd h: 0.130 (0.616 to -0.356), 3rd h: 0.162 (0.578 to -0.253), 4th h: 0.172 (0.724 to -0.379). FTc negatively correlated with SVV and CVP.

Conclusions

Both methods were able to monitor the trend changes of CO and equally guide fluid management, with a good degree of reliability, but their limits of agreement were

noted to be wide. This invites further development in the technology to improve their CO absolute values and improve precision

Keywords

CV physiology, cardiac output, fluid replacement, pediatrics, cardiometry, doppler

Introduction

The risks associating pulmonary artery catheter (PA) insertion in pediatrics limits its use for measuring the cardiac output (CO) by the thermodilution technique (TDT) particularly among infants. [1, 2]

Alternatively left cardiac output (CO) can be calculated non-invasively with electrical cardiometry (EC) utilizing the thoracic electrical bioimpedance via attached skin sensors, or less invasively through a Transoesophageal Doppler (TED) probe measuring the speed of moving blood in the aorta. Both devices were investigated previously by researchers and validated against TDT. [3-6]

The primary goal of the study is to monitor and compare values of CO obtained from Electrical Cardiometry (EC) to Transoesophageal Doppler (TED), as well as to assess both monitors role in fluid administration and compared the stroke volume variation (SVV) of EC to the corrected flow time (FTc) of TED. A second goal is to report their practical use in this age group and report their limitations.

Material and Methods

This randomized controlled trial was conducted at the National Liver Institute in Menoufia University, Egypt after written informed consents were obtained from the parents and following the Local Ethics and Research Committee approval of Faculty of Medicine, Menoufia University, Egypt, (March 2015). The trial was registered at the Pan African Clinical Trial registery (PACTR201703002141319).

Forty two (42) infants undergoing surgical hepatoportoenterostomy (Kasai surgical procedure) were equally divided into two equal groups for guided fluid intraoperative management: Electrical Cardiometry (EC) group (*n*=21) and Transoesophageal Doppler (TED) group (*n*=21). Sealed opaque envelopes were only opened by the Anaethesist on arrival to operating rooms suite to allocate the infant to his group. Parents were consented the night prior to surgery.

Both groups were monitored with EC and TED at all the measured times, In the EC group Anaesthesia providers were blinded to the TED readings, while in TED group they were blinded to the EC readings.

Infants with congenital heart disease and oesophageal malformation were excluded. All infants were subjected to preoperative assessment in the form of history, clinical examination, laboratory and radiological investigations. Trans-thoracic Echocardiography and upper gastro-esophageal endoscopy were performed for all infants.

Infants were kept fasting prior to the scheduled surgery (clear liquids, 2 h; breast milk, 4 h; infant formula, non-human milk, 6 h). General anesthesia was induced by the inhalation of 80% oxygen/air with 8% Sevoflurane until the patient loses consciousness and then the Sevoflurane concentration was gradually reduced to 4% and clinically adjusted accordingly with an anesthesia depth monitoring.

An intra-venous cannula was inserted and fentanyl (1 μg/kg) and rocuronium (0.9 mg/kg) administered to facilitate tracheal intubation with appropriate sized tracheal tube for each infant. General anaesthesia maintained with a mixture of 50% oxygen / air and sevoflurane (1 MAC end-tidal concentration).

Mechanical pressure controlled ventilation was performed in all infants using a semi-closed system adjusted to keep SaO2 more than 95% and end tidal CO2 between 25 mmHg and 35 mmHg (GE Datex Ohmeda S/5 Anesthetic 2 Delivery unit system arizant, USA).

Following induction of anesthesia, 4 F central venous catheter (AMECATH, 10th of Ramadan City-Egypt) single lumen central venous catheter was placed through the right internal jugular vein by ultrasound guided method (Sonosite-Nano max ultrasound system, Bothell-USA). Electrical Cardiometry (EC) (Electrical Cardiometry monitor, ICON Cardiotronics, Inc., La Jolla, CA 92307; Osypka Medical GmbH, Berlin, Germany) a developed technology to measure the cardiac output noninvasively via skin sensors was applied to all infants together with a minimal invasive paediatric transoesophagel doppler probes (TED) (CardioQp, Deltex medical, Chichester-UK).

EC derive CO from measurements of thoracic electrical bioimpedance, which is the electrical resistance to high frequency low amplitude current transmitted from upper and lower thorax electrodes. Originally, the Kubicek equation [7] was used to calculate the CO which was later modified by Bernstein. [8]

EC isolate changes in the electrical conductivity during cardiac cycle due to the changes in the orientation of erythrocytes (RBCs). During diastole, the RBCs in the aorta assume a random orientation, which causes the electrical current to meet more resistance, resulting in a lower measure of conductivity. During systole, the pulsatile flow causes the RBCs to align parallel to both the blood flow and the electrical current, resulting in a higher conductivity state. By analyzing the rate of change of conductivity before and after aortic valve opening and how fast the RBCs are aligning, EC can derive the peak aortic acceleration of blood and the left ventricular ejection time (flow time). The infant's data (age, weight, and height) will be registered. Four skin EC sensors were applied: on the forehead, on the left base of neck, on the lower left thorax at level of xiphoid and a fourth one on the lower left thorax approximately 5 cm below the 3rd electrode at the level of anterior axillary line and at the same side of the chest. The Electrical Cardiometry monitor will be connected to the sensor cable and the infant's data (age, weight, and height) will be fed to it.TED is a continuous, beat to beat, minimally invasive CO monitor that measures the blood flow velocity in the descending aorta by a paediatric oesophageal doppler probe with a specific 4 MHz wave Doppler transducer placed at the tip of a disposable flexible probe(KDP n-Kinder Doppler Probe). The infant's data (age, weight, and height) have to be registered in the Doppler monitor. The TED probe specific for a single-patient pediatric use is greased with a lubricating gel and passed orally into the mid-esophagus until aortic blood flow signals are best identified. Continuous point-to-point measurement of stroke distance (also known as velocity time integral, the area within the wave form) is performed by the TED for the calculation of stroke volume (mean of five cycles) using a paediatric normogram based on the patient's age, weight and height . CO (l.min)1) is then calculated as the product of stroke volume and the heart rate.[9]

Both EC and TED were set to measure cardiac output (CO) l/min., stroke volume (SV) ml/ beat and systemic vascular resistance (SVR) dynes/s/cm^5 during the surgical procedure and reported an hourly average at the same time of measurements. Both FTc (Flow Time Corrected) of TED and SVV (Stroke Volume Variation) of EC were monitored during mechanical ventilation under surgery and were used to provide data about the intravascular fluid status (Pre-Load) in each group to help guide fluid managements, but only one was made available for each group the other was reported but kept blind for the Anaethesist attending the surgery.

In both groups, an infusion of Ringer's acetate solution was administered intraoperative at constant rate (6 ml/kg/h) via an infusion pump to cover fluid deficit and basal fluid requirements. A Fluid challenge of (10ml/kg) colloid (Hydroxyethyl Starch) was given infused during a period of 20-40 min according to group infant randomly allocated to: In group EC: when SV of EC decrease by 15% of base line or SVV increase more than 15% and in group TED: when FTC and SV detected by TED decreased by more than 15% of their base line and to be repeated only if SV doesn't increase more than 15%. [10-13] Measurements were reported for both TED and EC groups: at Baseline (after induction of anesthesia), every hour till end of the surgery, this includes:

heart rate, blood pressure, urine output. Central venous pressure (CVP), total intra-operative fluid administration, complications and duration of surgery were all reported.

Statistical methods and Sample size

A sample size of 21 patients per group (number of groups=2) is the enough required sample per group to detect a standardized effect size (d) of 0.8 ml/m^2 of the primary outcome (stroke volume (SV)[12] as statistically significant with 80% power and at a significance level of 95% (alpha error allowed = 0.05). Sample size per group does not need to be increased to control for withdrawal bias. Sample size was calculated using G Power version 3.1.9.2. Data were collected and entered to the computer using SPSS (Statistical Package for Social Science) program for statistical analysis (Version 21). Data were entered as numerical or categorical, as appropriate, when Kolmogorov-Smirnov test revealed no significance in the distribution of variables, parametric statistics was carried out, while in the not-normally distributed data the non-parametric statistics was carried out. Data were described using minimum, maximum, mean, standard deviation and 95% CI of the mean for the normally distributed data. Data were described using minimum, maximum, median and inter-quartile range for not-normally distributed data. Categorical variables were described using frequency and percentage of total. Comparisons were carried out between two studied independent not-normally distributed subgroups using Mann-Whitney U test. Histograms with distribution curve, Box and Whiskers graph, bar chart and clustered bar chart were used accordingly. Chi-square test was used to test association between qualitative variables. Fisher's Exact test and Monte Carlo correction was carried out when indicated (expected cells less than 5). An alpha level was set to 5% with a significance level of 95%, and a beta error accepted up to 20% with a power of study of 80%. As most continuous variables were skewed, nonparametric approaches were used in the study. Baseline characteristics of quantitative variables between two groups were compared using Mann-Whitney for continuous and ordinal variables. Correction of p value for multiple testing was set P to 0.01 to detect significance (Bonforroni correction of multiple comparisons).

Results

Fifty infants were enrolled, but only 42 were studied. Three were excluded due to the inability to caputure an adequate TED signal, two with weak signals from the EC sensors during the surgical procedure and three due to failure to insert the central venous catheter. CONSORT flow presented in Figure 1.

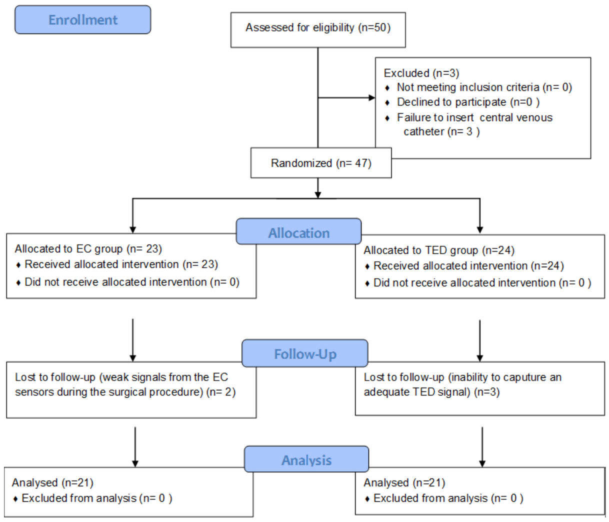

Figure 1. CONSORT flow diagram

Median [Interquartile] preoperative total Bilirubin plasma concentration (mg/dl), (*n*=42), 10.80 [8.50-12.70] mg/dl reduce postoperative to 9.00 (8.00-11.20), p<0.001. Table 1 demonstrates comparable age, weight, operative time and total fluid intake between both groups.

	TED (n=21)	EC (n=21)	p (value)
Age (days)	73 (62-80)	74 (58-86)	0.562 NS
Sex			
- Male	7 (33%)	11 (52%)	0.212 NS
- Female	14 (67%)	10 (48%)	
Weight (kg)	5.0 (5.0-5.5)	5.0 (4.2-5.2)	0.110 NS
Height (cm)	80 (70-80)	75 (70-80)	0.460 NS
Total operative duration (hr)	6.00 (5.00-6.00)	6.00 (5.00-6.00)	0.467 NS
Total Intraoperative fluid (ml)	300 (275-330)	300 (270-336)	0.594 NS

Table 1. Demographic data (age, sex, weight, height and body surface area BSA) differences between Electrical Cardiometry (EC) and Transesophageal Doppler group (TED) groups.
P<0.05 is considered statistically significant. NS = non-significant

Regardless of the allocated group, measured EC CO was noted to be constantly higher than TED CO (l/min) post-induction and mid-surgery respectively.

A good degree of reliability was found between TED CO and EC CO at all measuring points: at post-induction, (Intra-class correlation (ICC) =0.693, p<0.001), at first hour (ICC=0.744, p<0.001), at 2 hours (ICC=0.739, p<0.001), at 3 hours (ICC=0.769, p<0.001) and at 4 hours (ICC= 0.617, p=0.002). (Table 2), (Figure 2). A significant correlation existed between both CO. (Figure 3)

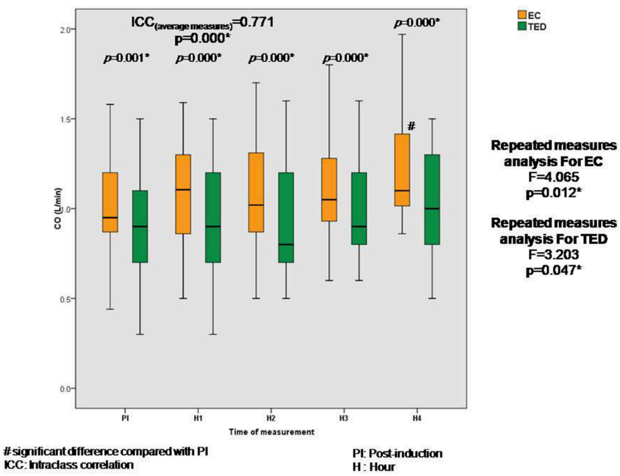

Figure 2. Box Plot graph of Cardiac Output (CO) (l/min) differences between EC and TED and groups at different intervals. TED= Transoesophageal Doppler; EC= Electrical Cardiometry; PI= Post-Induction; H1= First hour; H2= Second hour; H3= Third hour; H4= Forth hour.

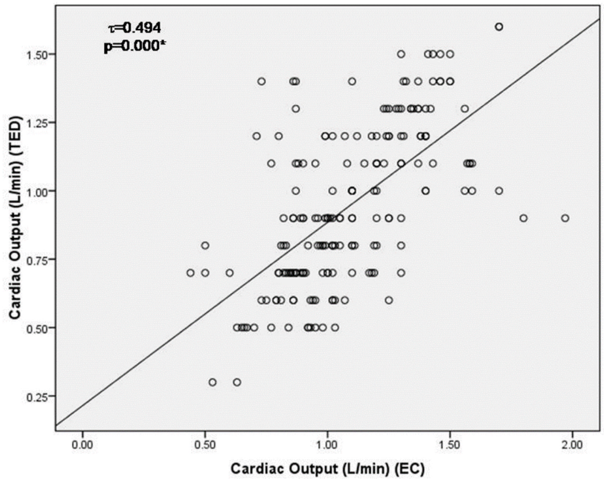

Figure 3. Scattered Plot graph of Cardiac Output (CO) (l/min) measured by Electrical Cardiometry (EC and Transesophageal Doppler (TED). Kendal Tau statistical correlation was used.

The Bland and Altman comparison of CO (l/min) between EC and TED showed reasonable bias [mean] but broad limits of agreement (±2 SD): Post-induction: 0.122 (0.636 to -0.391), Hour (h) 1: 0.147 (0.605 to -0.310), Hour (h) 2: 0.130 (0.616 to -0.356), Hour (h) 3: 0.162 (0.578 to -0.253), Hour (h) 4: 0.172 (0.724 to -0.379). (Figure 4)

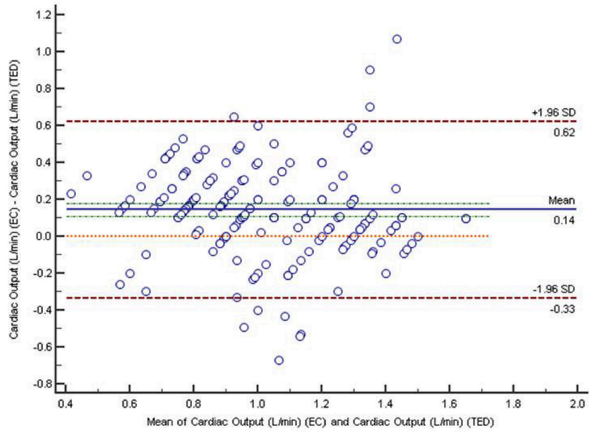

Figure 4. Bland Altman Analysis of degree of agreement between EC-CO and TED-CO. X-axis-mean CO from EC and TED [(TED-CO + EC-CO)]/2 and Y-axis—CO difference (ECCO-TEDCO). CO= Cardiac Output (l/min).

Scattered Plot graph for the Stroke Volume Variation (SVV) (%) of EC and Corrected flow time (m/sec) of TED demonstrated a negative correlation between all paired readings of all measuring times (Kendall tau correlation = 0.167, P<0.001). (Figure 5)

Both FTc of TED and SVV of EC were in correlation with the traditional central venous pressure changes, but this correlation was positive with FTc (Kendall tau correlation = 0.172, P<0.001) and negative with SVV (Kendall tau correlation = -0.26, P<0.001).

The diathermy interference affected both monitors, in addition TED probes required frequent repositioning as a result of the surgical manipulations.

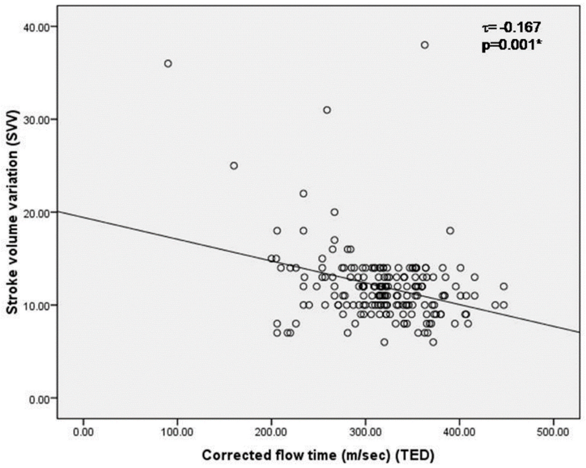

Figure 5. Scattered Plot graph of all paired readings at all measured times of Stroke Volume Variation (SVV) from EC and Corrected flow time (m/sec) from TED. TED, Transesophageal Doppler; EC, Electrical Cardiometry. Kendal Tau statistical correlation was used

Discussion

The results demonstrated that both EC and TED were able to track CO changes with a good degree of reliability between their measured values. This ability to follow the changes in CO in addition to guide intravenous fluids administration without the need for an invasive approach is of importance for this young age group, but more studies are still required to develop the technology in order to improve the precision of their absolute CO values.

The consistently lower TED CO values compared to EC CO reported at all the measuring point's needs an explanation, may be the position of the TED probes in the lower oesophageus facing the descending aorta, and could underestimate the CO as a result of the absence of the cerebral and upper limb blood flows in this part of aorta.

The W. Knirsch working group on non-invasive hemodynamics monitors among pediatrics observed a similar finding. They noted that the CO measured by the TED probes was lower than that measured by the pulmonary artery catheter thermodilution technique during heart catheterisation of 40 paediatric patients suffering from congenital heart defects. They suggested to measure each pediatric patient individual aortic diameter in order to improve the performance of TED CO readings and not to rely on previously prepared general population nomograms. [14]

Wodey et al studied a group of anesthetized children with both the esophageal Doppler and transcutaneous Doppler echocardiography. They observed a high variability of their mean aortic flow velocities and suggested that the absolute values of aortic flow velocities should be used with caution. [15]

Other researchers indicated that the aortic cross-sectional area can be one of the major contributors of error in TED CO values. To overcome this source of error, TED uses the minute distance (= time velocity integral multiplied by heart rate) measured in the descending aorta as a surrogate for CO, without the need to measure the cross sectional area. Changes in minute distance of TED after haemodynamic manipulation were in agreement with changes in CO measured by the gold standard thermodilution technique, but in contrast the absolute values of TED CO, were less acceptable. Measuring the true aortic diameter instead of the generated norm gram constant, could improve the accuracy of oesophageal Doppler, as recently demonstrated by Monnet et al study among adult patients with acute circulatory failure. [16-18]

Chew et al [19] reviewed the pediatric studies of CO measurements using Doppler technique back to the year 2002. They concluded that because of bias in children, the best results is to track changes rather than absolute values when using the transoesophageal approach which is similar to our findings.

In another clinical trial including 100 ventilated paediatric patients, Tibby S et al. demonstrated that transoesophageal Doppler ultrasonography was able to provide reasonable CO values across a wide paediatric age range and the changes in CO with time proved to be useful clinically. [16]

English JD and his colleagues demonstrated that TED may serve as a bed-side CO monitor among critically ill children over a wide range of patient size primarily for differentiating whether each child is in low-, mediumor high- CO hemodynamic status rather than to determine the absolute CO value. [20]

Raux also reported that the TED-derived stroke volume measurements during volatile anaesthesia is useful to predict and follow volume expansion responsiveness in neonates and infants with no myocardial dysfunction when their indexed stroke volume increased by more than 15%.[11,12]

The experience and support for the accuracy of these technologies for CO measurement varies, but the majority of researchers recognize the potential benefit for monitoring the trend of changes with time and the value it provides clinically to help guided management.

On the other side electric cardiometry was recently the focus of two recent studies by Cote C [13] and Liu CA. [21] In the first study Cote C illustrated that EC could be an additional important haemodynamic monitor that can track changes as a result of intraoperative haemodynamic interventions among children of all sizes. They reached to this conclusion after 292,012 measurements during 58,049 min of anesthesia, made in 374 of children between1 day to 19 years and 1 to 107 kg. In the second study by Liu CA reported their experience in monitoring cardiac output with electric cardiometry for infants subjected to a caudal regional block and their response CO changes to epinephrine. These two studies demonstrate the clinical benefit of noninvasive EC monitoring of CO in the immediate diagnoses and response by treatment. This was made easy by tracking the rapid CO changes and responses to medical treatment intervention.

Narula in recent study (2017) among 50 pediatrics with a variety of cardiac diseases undergoing cardiac catheterization with pulmonary artery catheters were able to reliably represent those measured CO values by the EC with a significant Intraclass Correlation Coefficient (ICC) of 0.789.[22]

Noori S and Rauch R were able to demonstrate an agreement between cardiac echocardiography, measurements and EC CO, but they noticed that a variation in the agreement among individual subjects can happen and reflecting the limitations of each technique.[23,24]

Dubost C study compared the monitoring performance of electrical bioreactance to the esophageal Doppler in pediatric population and came to the conclusion that cardiac output measured simultaneously by bio reactance and TED can be of a high percentage of variability.[25]

One of the beneficial advantages of EC monitoring when compared to TED is being noninvasive and light in weight as well as the expected low running cost of consumables needed to operate it, as it only requires electrocardiogram skin electrodes or sensors while the TED requires a sophisticated and more expensive Doppler beam probes.

The advantages of using noninvasive technologies for cardiac output monitoring and building experiences and developing the technology further in this young age need to be encouraged.

This young age group of days will always remain a challenge for anesthesiologist to monitor and diagnose their cardiac functions particularly when biliary atresia is associated with cardiac anolomy or dysfunction from high bilirubin. This study is one of the few studies using the minimal and noninvasive technology of CO to investigate the hemodynamics for young infants suffering from biliary atresia and undergoing surgery.

Limitations

One of the limitations of our study is the lack of comparison with thermodilution technique for CO measurement (PAC) mainly due to the difficulty in inserting PA catheters in this age group (median 73 days in TED and 74 days in EC) undergoing a Kasai surgical procedure, as well as the nature of the surgical procedure not in need for a PA catheter, but which otherwise would benefit from minimal or non-invasive technologies.

Conclusion

EC and TED were able to monitor the trend changes of CO in this young age group without exposing them to the risks of invasive procedures and equally guide fluid management, with a good degree of reliability between both, but their limits of agreement were wide. This invites further development in the technology to improve their CO absolute values and improve precision.

Conflict of interest: none

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