# WINDOW TO THE CIRCULATION®

Electrical Cardiometry™ Validations & Clinical Research


# ICON®
# AESCULON®

# Table of Contents



## NEONATAL



## PEDIATRIC



## ADULT

# Introduction

This booklet contains abstracts of several peer reviewed articles validating and exploring the clinical utility of **Electrical Cardiometry™** (EC) monitors, the ICON® and AESCULON® (shown on the cover) in adults, pediatrics, and neonates.

EC is able to provide noninvasive, continuous monitoring of cardiac output, stroke volume, and indicators of preload, contractility and afterload, easily and reliably. The technology only requires four sensors be placed on the patient's neck and chest (Figure 1). Via the sensors, the monitors apply a low-amplitude, high frequency current and measure the resulting change in conductance across the patient's chest.

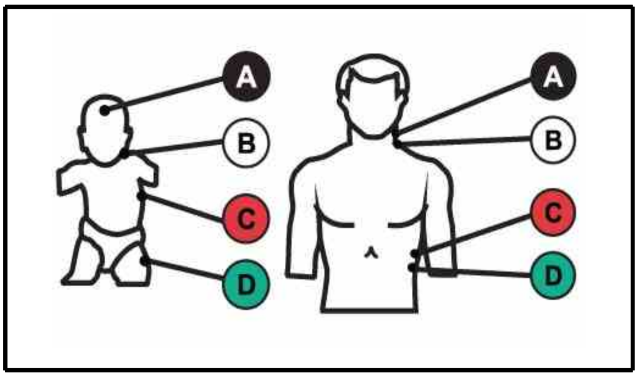

Figure 1: Sensor Placement

EC works analogously to Doppler echocardiography. Doppler looks at the propagation of sound waves through the aorta while EC looks at the propagation of electrical waves, which behave similarly. Using the model of **Electrical Velocimetry**, EC is able to measure the speed of blood flow and flow time in the aorta. Using a patient constant based on height and weight (instead of aortic diameter), the parameters are multiplied to get an accurate estimation of stroke volume (Figure 2).

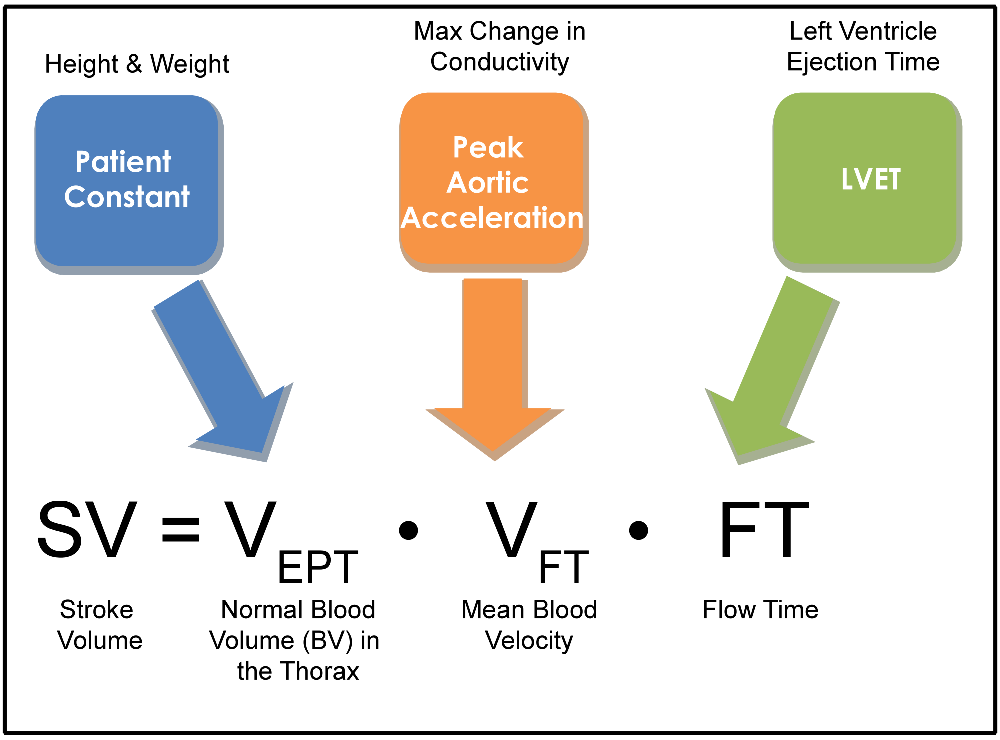

Figure 2: Patented Electrical Velocimetry Equation

# Non-invasive cardiac output measurement in low and very low birth weight infants: a method comparison

Grollmuss O[1] and Gonzalez P[2]

Frontiers in pediatrics 2 (2014)

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**Background:** Cardiac output (CO) measurement in low (LBW) and very low (VLBW) birth weight infants is difficult. Hitherto, sporadical transthoracic echocardiography (TTE) is the only non-invasive measurement method. Electrical velocimetry (EV) has been evaluated as an alternative in normal weight newborns.

**Objectives:** The study was designed to evaluate if EV could be interchangeable with TTE even in LBW and VLBW infants.

**Methods:** In 28 (17 LBW, 11 VLBW) pre-mature newborns, n=228 simultaneous TTE (trans-aortic Doppler), and EV measurements (134 LBW, 94 VLBW) of stroke volume (SV) and heart rate (HR) were performed, thereof calculating body weight indexed SV (=SV*) and CO (=CO*) for all patients and the subgroups. Method comparison was performed by Bland–Altman plot, method precision expressed by calculation of the coefficient of variation (CV).

**Results:** Mean CO* in all patients was 256.4±44.8 (TTE) and 265.3±48.8 (EV) ml/kg/min. Bias and precision were clinically acceptable, limits of agreement within the 30% criterion for method interchangeability (17). According to their different anatomic dimensions and pathophysiology, there were significant differences of SV(*), HR, and CO* for LBW and VLBW infants as well for inotropic treatment and ventilation mode.

**Conclusion:** Extending recent publications on EV/TTE comparison in newborns, this study suggests that EV is also applicable in LWB/VLBW infants as a safe and easy to handle method for continuous CO monitoring in the NICU and PCICU.

# Electrical velocimetry as a tool for measuring cardiac output in small infants after heart surgery

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Intensive care medicine 38.6 (2012): 1032-1039

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**Purpose:** Cardiac output (CO), the product of stroke volume (SV) and heart rate, is essential to guarantee organ perfusion, especially in the intensive care setting. As invasive measurement of CO bears the risk of complications there is a need for non-invasive alternatives. We investigated if electrical velocimetry (EV) and transthoracic Doppler (Doppler-TTE) are interchangeable for the non-invasive measurement of SV and able to reflect the post-surgical SV/CO trend.

**Methods:** Comparison of SV measurements by EV and Doppler-TTE was performed in 24 newborns after switch operation (n = 240 measurements). Three subgroups of measurements (=periods) were created according to the patients' status in the course of post-surgical CO recovery.

**Results:** Bland–Altman analysis found acceptable bias and limits of agreement for the interchangeability of the two methods. Mean overall SV was 3.7 ml with a mean overall bias of 0.28 ml (=7.6 %). The mean percentage error of 29 % was acceptable according to the method of Critchley and Critchley. Overall precision expressed by the coefficient of variation (CV) was 6.6 % for $SV_{TTE}$ and 4.4 % for $SV_{EV}$. $SV_{TTE}$ and $SV_{EV}$ medians in the three periods were significantly different and documented the post-surgical CO trend.

**Conclusions:** EV and Doppler-TTE are interchangeable for estimating SV. EV has the advantages of easy handling and allows continuous measurement.

# Continuous non-invasive cardiac output measurements in the neonate by electrical cardiometry: a comparison with echocardiography

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Archives of Disease in Childhood-Fetal and Neonatal Edition 97.5 (2012): F340-F343

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**Objective:** Electrical velocimetry (EV) is a noninvasive method of continuous left cardiac output monitoring based on measurement of thoracic electrical bioimpedance. The objective was to validate EV by investigating the agreement in cardiac output measurements performed by EV and echocardiography.

**Design/Methods:** In this prospective observational study, left ventricular output (LVO) was simultaneously measured by EV ($LVO_{ev}$) using Aesculon and by echocardiography ($LVO_{echo}$) in healthy term neonates during the first 2 postnatal days. To determine the agreement between the two methods, we calculated the bias (mean difference) and precision (1.96×SD of the difference). As $LVO_{echo}$ has its own limitations, the authors also calculated the 'true precision' of EV adjusted for echocardiography as the reference method.

**Results:** The authors performed 115 paired measurements in 20 neonates. $LVO_{ev}$ and $LVO_{echo}$ were similar (534±105 ml/min vs 538±105 ml/min, p=0.7). The bias and precision of EV were −4 and 234 ml/min, respectively. The authors found the true precision of EV to be similar to the precision of echocardiography (31.6% vs 30%, respectively). There was no difference in bias and precision between the measurements obtained in patients with or without a haemodynamically significant patent ductus arteriosus.

**Conclusions:** EV is as accurate in measuring LVO as echocardiography and the variation in the agreement between EV and echocardiography among the individual subjects reflects the limitations of both techniques.

# Non-invasive cardiac output monitoring during catheter interventions in patients with cavopulmonary circulations

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Cardiology in the young (2013): 1-5

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**Introduction:** Functionally univentricular hearts palliated with superior or total cavopulmonary connection result in circulations in series. The absence of a pre-pulmonary pump means that cardiac output is more difficult to adjust and control. Continuous monitoring of cardiac output is crucial during cardiac catheter interventions and can provide new insights into the complex physiology of these lesions.

**Materials and methods:** The ICON cardiac output monitor was used to study the changes in cardiac output during catheter interventions in 15 patients (median age: 6.1 years, range: 4.8–15.3 years; median weight: 18.5 kg, range: 15–63 kg) with cavopulmonary circulations. A total of 19 interventions were undertaken in these patients and the observed changes in cardiac output were recorded and analyzed.

**Results:** Cardiac output was increased with creation of stent fenestrations after total cavopulmonary connection (median increase of 22.2, range: 6.7%–28.6%) and also with drainage of significant pleural effusions (16.7% increase). Cardiac output was decreased with complete or partial occlusion of fenestrations (median decrease of 10.6, range: 7.1%–13.4%). There was a consistent increase in cardiac output with stenting of obstructive left pulmonary artery lesions (median increase of 7.7, range: 5%–14.3%, $p<0.007$).

**Conclusions:** ICON provides a novel technique for the continuous, non-invasive monitoring of cardiac output. It provides a further adjunct for monitoring of physiologically complex patients during catheter interventions. These results are consistent with previously reported series involving manipulation of fenestrations. This is the first report identifying an increase in cardiac output with stenting of obstructive pulmonary arterial lesions.

# Non-invasive measurement of cardiac output in obese children and adolescents: comparison of electrical cardiometry and transthoracic Doppler echocardiography

Rauch R, Welisch E, Lansdell N, ... and Norozi K

Journal of clinical monitoring and computing 27.2 (2013): 187-193

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The objective of this study was to evaluate the reliability and accuracy of electrical cardiometry (EC) for the noninvasive determination of cardiac output (CO) in obese children and adolescents. We compared these results with those obtained by transthoracic echocardiography. Sixty-four participants underwent simultaneous measurement of CO. Cardiac output was measured by EC using the ICON device. Simultaneously CO was determined by using transthoracic Doppler echocardiography from parasternal long-axis and apical view. The median age was 12.52 years (range 7.9–17.6 years) and 36 (56 %) were female. A strongly significant correlation was found between the $CO_{EC}$ and $CO_{Echo}$ measurements ($p < 0.0001$, $r = 0.91$). Significant correlations were also found between CO and age ($r = 0.37$, $p = 0.002$), weight ($r = 0.57$, $p < 0.0001$), height ($0.60$, $p < 0.0001$) and BMI ($r = 0.42$, $p = 0.001$). The mean difference between the two methods ($CO_{EC} – CO_{Echo}$) was 0.015 l $min^{-1}$. According to the Bland and Altman method, the upper and lower limits of agreement, defined as mean difference ± 2 SD, were +1.21 and -0.91 l $min^{-1}$, respectively. Compared to the transthoracic Doppler echocardiography, Electrical Cardiometry provides accurate and reliable CO measurements in obese children and adolescents.

# Non-invasive cardiac output and oxygen delivery measurement in an infant with critical anemia

Steil G, Eckstein O, Caplow J, Agus M, Walsh B, and Wong J

Journal of clinical monitoring and computing 25.2 (2011): 113-119

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**Objective:** To assess the combination of a noninvasive blood oxygen content ($CaO_2$) monitor and a noninvasive cardiac output (CO) monitor to continuously measure oxygen delivery ($DO_2$; $DO_2 = CaO_2 \times CO$).

**Methods:** $DO_2$ was assessed during blood transfusions in an infant with acute hemolytic anemia following admission (~48 h). $CaO_2$ was measured by Pulse Co-Oximetry, which also provides estimates of hemoglobin (Hgb) concentration and percent oxygen saturation. CO was measured by Electrical Velocimetry, which also provides an estimate of stroke volume (SV). Lactate levels, an indirect measure of adequate $DO_2$, were assessed during the initial 8 h following admission.

**Results**: Incremental blood transfusions during the first 36 h increased Hgb from 2.7 to 9.5 g/dL during which time heart rate (HR) normalized from 156 to 115 beats/min. Lactate levels decreased from 20 to 0.8 mmol/L in the first 7 h. Non-invasive Hgb and $CaO_2$ measurements were well correlated with invasive Hgb and $CaO_2$ measures ($r^2 = 0.88$; $P = 0.019$; $r^2 = 0.86$; $P = 0.0074$, respectively). CO decreased from 2.47±0.06 to 1.28±0.02 L/min and SV decreased from 15.9±0.4 to 11.1±0.2 mL/beat. Mean arterial blood pressure was stable throughout the admission with systemic vascular resistance increasing from 407.6±15.2 to 887.7±30.1 dynes-s/cm$^5$. $DO_2$ was estimated to increase from 120.2±18.9 to 182.4±5.6 mL $O_2$/min.

**Conclusions:** Non-invasive continuous CO and $CaO_2$ monitors are shown in this single case to provide continuous $DO_2$ measurement. The ability to assess $DO_2$ may improve hemodynamic monitoring during goal directed therapies.

# Electrical velocimetry for measuring cardiac output in children with congenital heart disease

Norozi K[1], Beck C[1], Osthaus W[2], Wille I[1], Wessel A[1], and Bertram H[1]

British journal of anaesthesia 100.1 (2008): 88-94

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**Background:** The purpose of this study was to evaluate the agreement of cardiac output measurements obtained by electrical velocimetry ($CO_{EV}$) and those that derived from the direct Fick-oxygen principle ($CO_F$) in infants and children with congenital heart defects.

**Methods:** Simultaneous measurements of $CO_{EV}$ and $CO_F$ were compared in 32 paediatric patients, aged 11 days to 17.8 yr, undergoing diagnostic right and left heart catheterization. For non-invasive measurements of cardiac output by electrical velocimetry, which is a variation of impedance cardiography, standard surface electrodes were applied to the left side of the neck and the left side of the thorax at the level of the xiphoid process. Cardiac output determined using direct Fick-oxygen principle was calculated by direct measurement of oxygen consumption ($VO_2$) and invasive determination of the arterio-venous oxygen content difference.

**Results:** An excellent correlation (r=0.97) was found between $CO_{EV}$ and $CO_F$ (P<0.001). The slope of the regression equation [0.96 (SD 0.04)] was not significantly different from the line of identity. The bias between the two methods ($CO_{EV}$–$CO_F$) was 0.01 litre $min^{-1}$ and the limits of agreement, defined as the bias (2 SD), were -0.47 and +0.45 litre $min^{-1}$-.

**Conclusions:** $CO_{EV}$ demonstrates acceptable agreement with data derived from $CO_F$ in infants and children with congenital heart disease. The new technique is simple, completely non-invasive, and provides beat-to-beat estimation of CO.

# Comparison of electrical velocimetry and transpulmonary thermodilution for measuring cardiac output in piglets

Osthaus A, Huber D, Beck C, Winterhalter M, Boethig D, Wessel A, and Suempelmann R

Pediatric Anesthesia 17.8 (2007): 749-755

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**Background:** Monitoring of cardiovascular function is essential during major pediatric and pediatric cardiac surgery. Invasive monitoring of cardiac output (CO) and oxygen delivery is expensive and sometimes associated with adverse events. Therefore, we investigated the accuracy of a new noninvasive CO monitoring device using electrical velocimetry (EV) in comparison with the more invasive transpulmonary thermodilution (TPTD) method.

**Methods**: In five fasted, anesthetized and mechanically ventilated piglets, CO was measured simultaneously using EV and TPTD under normal conditions, volume loading, inotropic support and exsanguination.

**Results:** In five piglets, 169 measurements could be performed. The correlations between EV–CO and TPTD–CO were significant for absolute values ($P < 0.0001$, $r = 0.82$) and relative changes from baseline ($P < 0.0001$, $r = 0.93$). The receiver operating characteristic (ROC) curve analysis of the relative changes of the EV–CO values in relation to the first EV–CO measurement showed a sensitivity of 91% and specificity of 94% (AUC 0.974, 95% CI 0.96–0.99). Changes in TPTD–CO greater than 15% lead to a change of EV–CO in the same direction in 93%. Bland–Altman analysis showed a mean difference between the two methods of -0.63 $l\ min^{-1}$ with an SD of 0.64 $l\ min^{-1}$. The lower and upper limits of agreement were -1.88 and 0.62 $l\ min^{-1}$, percentage limit of agreement was ±82.8%.

**Conclusions:** The results show that EV is a safe, simple, noninvasive and cost-effective method for continuous trend monitoring of CO in piglets. The agreement of the EV–CO with TPTD–CO is not good enough to replace the standard method in our animal model. A correction factor for body habitus in piglets may be beneficial.

# Real-time heart rate entropy predicts the need for lifesaving interventions in trauma activation patients

Mejaddam A, Birkhan O, Sideris A, Van der Wilden G, Imam A, Hwabejire J, ... and King D

Journal of Trauma and Acute Care Surgery 75.4 (2013): 607-612

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**Background:** Heart rate complexity (HRC), commonly described as a ''new vital sign,'' has shown promise in predicting injury severity, but its use in clinical practice has been precluded by the absence of real-time data. This study was conducted to evaluate the utility of real-time, automated, instantaneous, hand-held heart rate entropy analysis in predicting the need for lifesaving interventions (LSIs). We hypothesized that real-time HRC would predict LSIs.

**Methods:** Prospective enrollment of patients who met criteria for trauma team activation was conducted at a Level I trauma center (September 2011 to February 2012). A novel, hand-held, portable device was used to measure HRC (by sample entropy) and time-domain heart rate variability continuously in real time for 2 hours after the moment of presentation. Electric impedance cardiography was used to determine cardiac output. Patients who received an LSI were compared with patients without any intervention (non-LSI). Multivariable analysis was performed to control for differences between the groups.

**Results:** Of 82 patients enrolled, 21 (26%) received 67 LSIs within 24 hours of hospital arrival. Initial systolic blood pressure was similar in both groups. LSI patients had a lower Glasgow Coma Scale (GCS) score (9.2 [5.1] vs. 14.9 [0.2], $p < 0.0001$). The mean (SD) HRC value on presentation was 0.8 (0.6) in the LSI group compared with 1.5 (0.6) in the non-LSI group ($p < 0.0001$). With the use of logistic regression, initial HRC was the only significant predictor of LSI. A cutoff value for HRC of 1.1 yields sensitivity, specificity, negative predictive value, and positive predictive value of 86%, 74%, 94%, and 53%, respectively, with an accuracy of 77% for predicting an LSI.

**Conclusion:** Decreased HRC on hospital arrival is an independent predictor of the need for LSI in trauma activation patients. Real-time HRC may be a useful adjunct to standard vital signs monitoring and predicts LSIs.

# Real-time sample entropy predicts life-saving interventions after the Boston Marathon bombing

Peev M, Naraghi L, Chang Y, DeMoya M, Fagenholz P, Yeh D, ... and King D

Journal of critical care 28.6 (2013): 1109-e1

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**Purpose:** Identifying patients in need of a life-saving intervention (LSI) during a mass casualty event is a priority. We hypothesized that real-time, instantaneous sample entropy (SampEn) could predict the need for LSI in the Boston Marathon bombing victims.

**Materials and methods:** Severely injured Boston Marathon bombing victims (n = 10) had sample entropy (SampEn) recorded upon presentation using a continuous 200-beat rolling average in real time. Treating clinicians were blinded to real-time results. The correlation between SampEn, injury severity, number, and type of LSI was examined.

**Results:** Victims were males (60%) with a mean age of 39.1 years. Injuries involved lower extremities (50.0%), head and neck (24.2%), or upper extremities (9.7%). Sample entropy negatively correlated with Injury Severity Score (r=−0.70; P=.023), number of injuries (r=−0.70; P=.026), and the number and need for LSI (r = −0.82; P = .004). Sample entropy was reduced under a variety of conditions.

| | SampEn (mean ± SD) | P |
|---|---|---|
| Amputation, n = 5 | 0.7 ± 0.3 | |
| No amputation, n = 5 | 1.9 ± 0.8 | .027 |
| Transfusion, n = 5 | 0.7 ± 0.3 | |
| No transfusion, n = 5 | 1.9 ± 0.8 | .027 |
| Intubation, n = 6 | 0.8 ± 0.3 | |
| No intubation, n = 4 | 2.1 ± 0.7 | .027 |
| Vasopressors, n = 7 | 0.8 ± 0.3 | |
| No vasopressors, n = 3 | 2.4 ± 0.3 | .004 |

**Conclusions:** Sample entropy strongly correlates with injury severity and predicts LSI after blast injuries sustained in the Boston Marathon bombings. Sample entropy may be a useful triage tool after blast injury.

# Comparison of electrical velocimetry and thermodilution techniques for the measurement of cardiac output

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Acta Anaesthesiologica Scandinavica 51.10 (2007): 1314-1319

Departments of [1]Intensive Care Medicine and [2]Anaesthesiology, University Hospital RWTH Aachen, Aachen, and [3]Department of Intensive Care Medicine, Helios Klinikum Berlin Buch, Berlin, Germany

**Aim:** To compare a new method of non-invasive determination of cardiac output based on electrical velocimetry (EV-CO) with invasive thermodilution methods.

**Methods:** Fifty critically ill patients were enrolled into the study. EV-CO was compared with cardiac output measured by a pulmonary artery catheter (PA-CO) in one group (n =25) and by a femoral artery catheter (PiCCO-CO) in a second group (n= 25), by simultaneous measurements. Standard electrocardiography electrodes were used for non-invasive measurements, and EV-CO was calculated using the Bernstein–Osypka equation. The invasive measurements of PA-CO and PiCCO-CO were made by the injection of iced 0.9% saline and the recording of thermodilution curves.

**Results:** The precision values of EV-CO, PA-CO and PiCCO-CO measurements were ± 0.46 [95% confidence interval (95% CI), ± 0.06], ± 0.57 (95% CI, ± 0.09) and ± 0.48 l/min (95% CI, ± 0.08 l/min), respectively. The mean differences between EV-CO and PA-CO or PiCCO-CO were –0.05 ± 0.71 and 0.22 ± 0.78 l/min, respectively. The lower and upper limits of agreement for the comparison of EV-CO with PA-CO were -1.47 and 1.37 l/min (95% CI, ± 0.25 l/min), respectively. In the comparison of EV-CO and PiCCO-CO, lower and upper limits of –1.34 and 1.78 l/min (95% CI, ± 0.27 l/min) were found. The percentage errors between EV-CO and PA-CO or PiCCO-CO were 26.5% and 26.4%, respectively.

**Conclusions:** The values of cardiac output were statistically comparable between the groups. Therefore, electrical velocimetry is a suitable method to evaluate haemodynamic variables with clinically acceptable accuracy.

# Comparison of electrical velocimetry and transoesophageal Doppler echocardiography for measuring stroke volume and cardiac output

Schmidt C, Theilmeier G, Van Aken H, Korsmeier P, Wirtz S, Berendes E, Hoffmeier A, and Meissner A

British journal of anaesthesia 95.5 (2005): 603-610

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**Background:** Impedance cardiography (ICG) has been used extensively to estimate stroke volume (SV) and cardiac output (CO) from changes of thoracic electrical bioimpedance (TEB). However, studies comparing ICG with reference methods have questioned the reliability of this approach. Electrical velocimetry (EV) provides a new algorithm to calculate CO from variations in TEB. As the transoesophageal Doppler echocardiographic quantification of CO (TOE–CO) has emerged as a reliable method, the purpose of this study was to determine the limits of agreement between CO estimations using EV (EV–CO) and TOE–CO.

**Methods:** Standard ECG electrodes were used for non-invasive EV–CO measurements. These were placed on 37 patients scheduled for coronary artery surgery necessitating transoesophageal echocardiography monitoring. Simultaneous EV–CO and TOE–CO measurements were recorded after induction of anaesthesia. EV–CO was calculated using the Bernstein–Osypka equation. TOE–CO was measured across the aortic valve using continuous-wave Doppler echocardiography and a triangular orifice model.

**Results:** A significant high correlation was found between the TOE–CO and the EV–CO measurements ($r^2$=0.86). Data were related linearly. The slope of the line (1.10 (SE 0.07)) was not significantly different from unity, and the point at which it intersected the ordinate (-0.46 (0.32) litre $min^{-1}$) was not significantly different from zero. Bland–Altman analysis revealed a bias of 0.18 litre $min^{-1}$ with narrow limits of agreement (-0.99 to 1.36 litre $min^{-1}$).

**Conclusions:** The agreement between EV–CO and TOE–CO is clinically acceptable, and these two techniques can be used interchangeably.

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