

# The pilot study of role of electrical cardiometry in non-invasive assessment of hemodynamic parameters in patients with pulmonary arterial hypertension (RCD code: II-1A.1)

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## Abstract

**Background:** Electrical cardiometry (EC) technique could estimate cardiac output (CO), cardiac index (CI) and other parameters related to cardiac contractility and fluid status by measuring the thoracic electrical bioimpedance. We hypothesized that EC could assess right ventricle (RV) hemodynamic function in patients diagnosed with pulmonary arterial hypertension (PAH). **Results:** In our pilot study, enrolling 23 PAH patients, we observed a significant correlation ( $r = 0.71$ ;  $p < 0.001$ ) between thermodilution CO measurement results ( $4.59 \pm 1.05$  l/min) and CO results obtained by EC ( $4.86 \pm 1.20$  l/min) and between systemic vascular resistance calculated by EC monitor and obtained during right heart catheterization (RHC) ( $r = 0.68$ ;  $p = 0.002$ ). Furthermore, EC parameter index of contractility (ICON) significantly correlated with tricuspid annular plane systolic excursion assessed by echocardiography ( $r = 0.57$ ;  $p = 0.01$ ). **Conclusions:** RHC cannot be replaced in obtaining accurate results of CO, however EC technique provides feasible insight into RV function at the bedside or outpatient care. JRC D 2017; 3 (2): 44–49

**Key words:** rare disease, electrical cardiometry, right heart catheterization, pulmonary arterial hypertension, hemodynamic measurements

## Background

The electrical cardiometry (EC) technique could estimate cardiac output (CO), cardiac index (CI) and other parameters related to cardiac contractility and fluid status by measuring the thoracic electrical bioimpedance [1]. It has been validated and is utilized in various cardiovascular disorders, however its diagnostic relevance in patients with pulmonary arterial hypertension (PAH) or right ventricular (RV) failure is unclear [2]. In PAH patients, RV failure is a very common cause of deterioration of patients' status and often leads to death. CI, assessed by thermodilution method during right heart catheterisation (RHC), belongs to the most important parameters describing the clinical status. According to

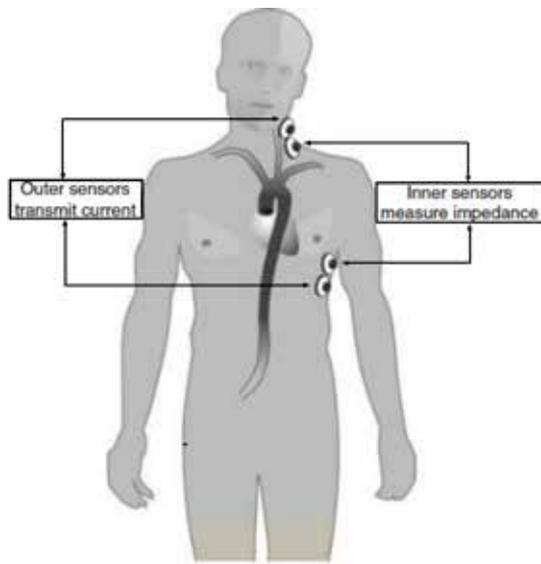
the 2015 The European Society of Cardiology (ESC) / European Respiratory Society (ERS) guidelines, patients with CI lower than 2 litres/min/m<sup>2</sup> are in high risk (>10%) of 1-year mortality [3]. EC could be an opportunity to assess hemodynamic state of patient in a non-invasive way.

Based on changes of thoracic electrical bioimpedance during the cardiac cycle and on the input of body mass, EC estimates stroke volume (SV). The model of EC assumes that the alignment of erythrocytes in the aorta is responsible for a significant change in the impedance after the aortic valve opening and relies on a change in impedance dependent on the blood flow in the aorta. Then a mean velocity index is empirically derived from a peak amplitude measurement assumed to be an index of peak aortic accelera-

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**Figure 1.** An array of 4 surface electrocardiography electrodes attached to the left side of the patient's neck and the lower thorax (approximately at the level of the xiphoid process). Source of image: commons.wikimedia.org

tion of blood flow and a measurement of flow time. EC monitoring also provides estimation of systemic vascular resistance (SVR), information about thorax fluid capacity or contractility of the heart muscle [1,4].

RHC is a gold standard to directly acquire hemodynamic measurements e.g. pulmonary artery pressures, central venous / right atrial pressure (CVP/RAP) or cardiac output (determined by thermodilution or Fick method) [3]. However, there is a need for non-invasive, fast assessments of crucial parameters like CO at bedside or in outpatient care.

In this pilot study we investigated the usefulness of EC in assessment of hemodynamic status in twenty-three PAH patients in comparison to the results obtained during RHC and echocardiography.

## Methods

EC parameters were assessed by portable non-invasive hemodynamic monitor ICON (Osypka Medical GmbH, Berlin, Germany) in 23 patients diagnosed with PAH shortly after RHC and echocardiography. We placed 4 surface electrocardiographic (ECG) electrodes to the left side of the patient's neck and the lower thorax (approximately at the level of the xiphoid process) (Figure 1). An electrical alternating current (AC) of constant amplitude is applied via the pair of outer electrodes to the thorax and in particular – because blood is the most conducting tissue in the thorax – the ascending and descending aorta. The resulting voltage and a surface ECG are obtained via the inner pair of electrodes. The ratio of applied current and measured voltage equals the conductivity, which is recorded over time. In this way various parameters were obtained like SV, heart rate (HR), CO, CI, SVR, index of contractility (ICON) and its variation (VIC), total thorax fluid capacity (TFC) [5].

Inclusion criteria were: diagnosis of PAH, no changes in therapy within two months prior the start of the study and written approval for participation in the study. Exclusion criteria were: World Health Organisation (WHO) functional class IV, Eisenmenger syndrome and other causes of pulmonary hypertension, patients with arrhythmias or aortic regurgitation. A diagnosis of pre-capillary pulmonary hypertension (PH) was determined by the RHC [mean pulmonary artery pressure (mPAP)  $\geq 25$  mm Hg and pulmonary capillary wedge pressure (PCWP)  $\leq 15$  mm Hg at rest]. Other causes of PH were ruled out by pulmonary function tests, computed tomography (CT), ventilation perfusion scintigraphy and blood tests. Patients with PAH due to congenital heart diseases were excluded from the study.

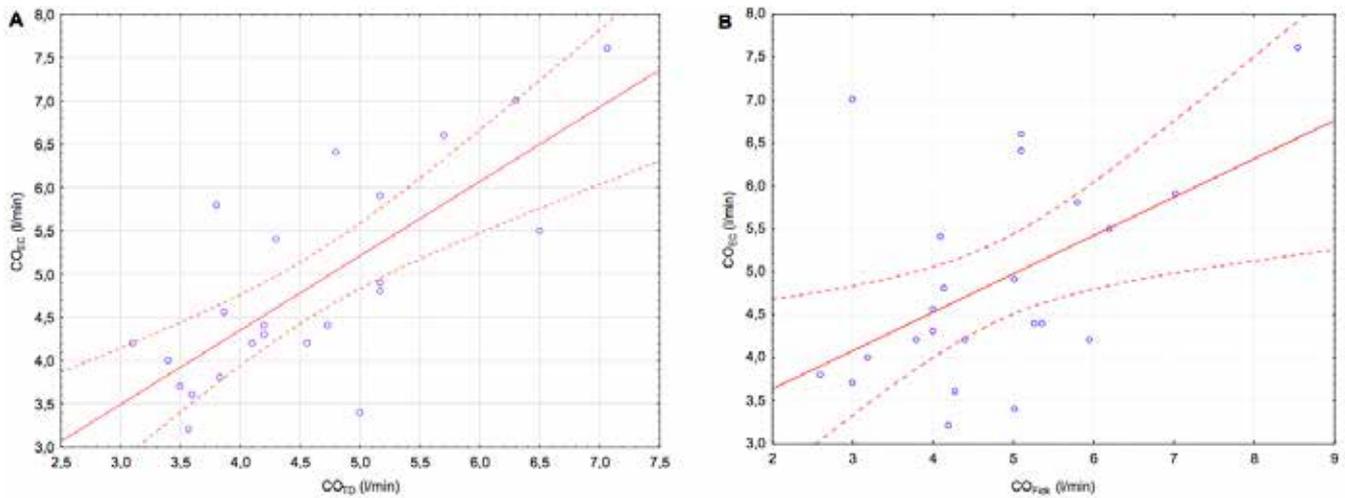
All patients underwent RHC. The following haemodynamic variables were measured: mPAP, mean right atrial pressure (mRAP), mean pulmonary artery wedge pressure (PAWP). Indirect Fick principle as well as thermodilution method were used to calculate CO, CI and pulmonary vascular resistance (PVR). Oxygen consumption was assumed from equation suggested by Bergstra [6].

Echocardiographic study was performed to assess function of the right heart. Quantification of two-dimensional and Doppler echocardiography data, including RV and atrium (RA) dimensions (apical 4-chamber view), peak tricuspid regurgitation jet velocity (using colour-coded Doppler), the maximum velocity of the regurgitation jet ( $V_{max}$ ) (using continuous-wave Doppler), acceleration time ( $A_cT$ ) (time to peak velocity of the pulsed wave Doppler profile obtained in the RV outflow tract). Simplified Bernoulli equation ( $TRPG = 4V^2$ ) was implemented to obtain systolic gradient of pressures between the RV and the right atrium – tricuspid regurgitant peak gradient (TRPG). Estimated pulmonary artery pressure (ePAP) based on the peak tricuspid regurgitation velocity taking into account estimated right atrial pressure (eRAP) was also obtained [7]. eRAP was estimated using the inferior vena cava (IVC) diameter and its respiratory variation in the subcostal short axis view. RV systolic function was assessed by measuring the tricuspid annular plane systolic excursion (TAPSE).

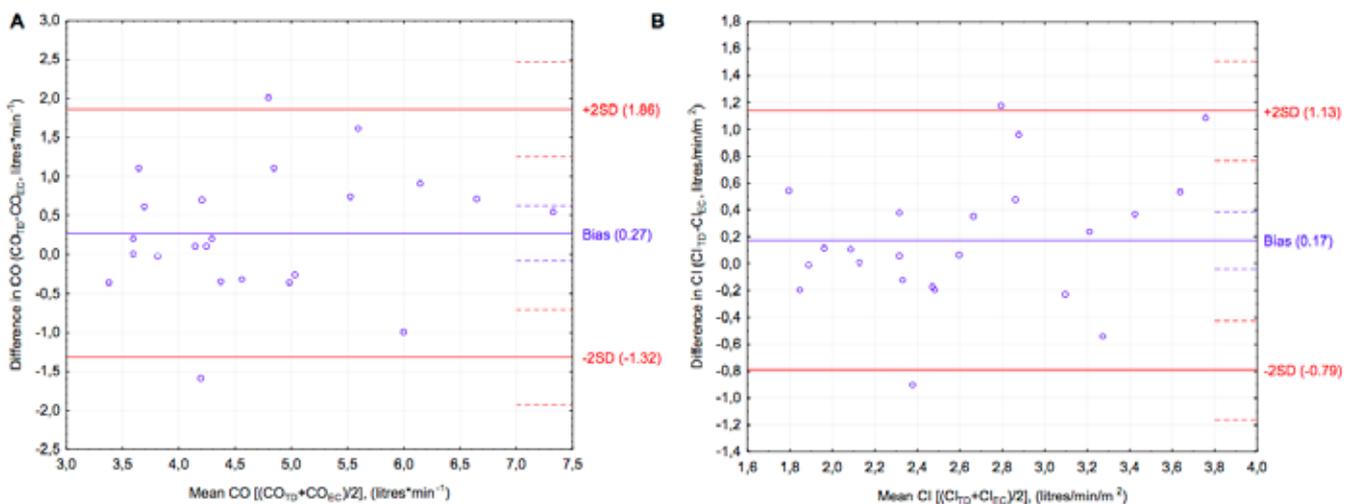
Statistical analysis was performed to assess the correlations between parameters obtained using both invasive and non-invasive techniques (evaluated using Spearman's correlation coefficients). The distribution of all variables was verified with Kolmogorov-Smirnov test. Data are expressed as mean and standard deviation (SD) or median values with interquartile range (IQR) appropriately. Statistical analysis was performed using t-student or Mann-Whitney U test for continuous data depending on distribution or  $\chi^2$  test for categorical variables. The bias and precision between the techniques were analysed by using the method of Bland and Altman.  $P < 0.05$  was deemed statistically significant. A statistical software package Statistica 10 (USA) was used for analysis.

## Results

The study enrolled 23 stable patients ( $54.1 \pm 17.2$  years old), 13 females (57%) with confirmed diagnosis of PAH, in WHO functional class II and III. The majority of cases (74%,  $n = 17$ ) had idiopathic PAH (69.5%,  $n = 16$ ) and the others PAH associated with connective tissue diseases (30.5%,  $n = 7$ ). Mean weight of patients



**Figure 2.** Comparison of cardiac output measured with electrical cardiometry ( $CO_{EC}$ ), the Fick method ( $CO_{Fick}$ ), and the thermodilution method ( $CO_{TD}$ ). (A) Correlation of  $CO_{EC}$  and  $CO_{TD}$ ;  $r = 0.71$ ,  $p < 0.001$  (B) Correlation of  $CO_{EC}$  and  $CO_{Fick}$ ;  $r = 0.43$ ,  $p = 0.03$



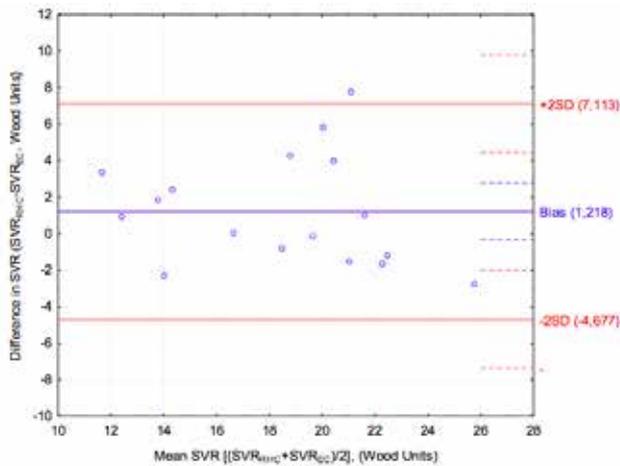
**Figure 3.** Bland-Altman plot of difference in (A) cardiac output obtained by thermodilution method during right heart catheterization ( $CO_{TD}$ ) and estimated by electrical cardiometry ( $CO_{EC}$ ); (B) cardiac index obtained by thermodilution method during right heart catheterization ( $CI_{TD}$ ) and estimated by electrical cardiometry ( $CI_{EC}$ )

was  $73.76 \pm 18.4$  kg and mean body surface area  $1.81 \pm 0.21$  m<sup>2</sup>. All patients were receiving specific PAH treatment at the time of the study. Most PAH patients had WHO class III functional limitations (60%,  $n = 14$ ), median 6-minute walk test distance was 390 m (350–461). Group characteristics, echocardiographic findings and hemodynamic data are summarized in Table 1. EC results are presented in Table 2.

We observed significant correlation ( $r = 0.71$ ;  $p < 0.001$ , Figure 2A) between thermodilution CO measurement ( $CO_{TD}$ ) results ( $4.59 \pm 1.05$  l/min) and CO results obtained by EC ( $CO_{EC}$ ) ( $4.86 \pm 1.20$  l/min). Worse correlation was found between Fick method CO and  $CO_{EC}$  ( $r = 0.43$ ,  $p = 0.03$ , Figure 2B). CI measurements followed the same pattern ( $CI_{TD}$  and  $CI_{EC}$   $r = 0.71$ ,  $p < 0.001$ ; Fick method CI and  $CI_{EC}$   $r = 0.52$ ,  $p = 0.09$ ). Bland-Altman analysis indicated a bias (mean difference) between  $CO_{TD}$  and  $CO_{EC}$  of

0.27 l/min (Figure 3A) and between  $CI_{TD}$  and  $CI_{EC}$  of 0.17 l/min/m<sup>2</sup> (Figure 3B).

Furthermore, EC monitoring provided information about left ventricle afterload represented by SVR. There was a significant correlation between SVR calculated by EC monitor and SVR obtained during RHC ( $r = 0.68$ ;  $p = 0.002$ , Figure 4). One of the major question was, if this method, developed for chronic heart failure with reduced ejection fraction, could also predict right-sided cardiac function. Index of contractility (ICON) significantly correlated with parameter TAPSE assessed by echocardiography ( $r = 0.57$ ;  $p = 0.01$ ) and with  $CO_{EC}$  ( $r = 0.52$ ;  $p = 0.01$ ). However, EC total fluid capacity (TFC) results did not correlate with neither of parameters used in PAH to guide fluid management like IVC diameter or CVP ( $p = ns$ ). Furthermore, RA pressure and mixed venous oxygen saturation did not correlate with any of EC parameters.



**Figure 4.** Bland-Altman plot of difference in systemic vascular resistance obtained during right heart catheterization ( $SVR_{RHC}$ ) and estimated by electrical cardiometry ( $SVR_{EC}$ )

## Discussion

This is, to our knowledge, the first study, which attempted to evaluate a potential role of non-invasive assessment of hemodynamic profile using EC in patients with PAH.

It was previously established that RV function is an important determinant of functional state, exercise capacity and survival in patients with PAH [3]. Importance of RV function in PAH is further reflected by the prognostic significance of RV functional parameters like RAP, SV and CO. However, how to quickly evaluate RV function and what variables might be most clinically relevant at the bedside remain uncertain.

We assumed that EC, which normally is used to obtain left ventricle parameters especially in left ventricular failure, could provide good estimation of RV hemodynamic profile, crucial to PAH patients assessment. To avoid any deviations of EC results arising from shunts between heart chambers, we excluded from the study patients with uncorrected congenital heart defects.

Continuous CO and hemodynamic monitoring has gathered much interest as a mainstay in the critical care setting, giving physicians a tool for managing fluid, titrations, and most importantly patient recovery [1]. When used in conjunction with goal-directed fluid administration, measures of CO have been shown to reduce morbidity, reduce length of hospital stay, and improve overall patient outcome [8]. Traditionally, a pulmonary artery catheter (PAC) placed in the pulmonary artery had been required to obtain CO, with the associated risks and complications of an invasive procedure. In clinical practice, the measurement of CO is necessary in comprehensive assessment of clinical status. Measurements of CO, based on the thermodilution technique, requires the catheterization of arterial or central venous vessels. This invasive technique is being criticized because of its uncertain benefit–risk ratio [8–10]. Therefore, many less or even non-invasive methods have been explored in an effort to reduce the risk to patients and to improve the benefit–risk ratio. The new technique of EC can determine CO

**Table 1. Basic characteristics of the study patients**

Age, years	54.1 ± 17.2
Sex (females), % (n)	57 (13)
BSA, m <sup>2</sup>	1.81 ± 0.21
6MWT, m	390 <sup>#</sup> [350–461]
Heart rate, beats/minute	75.68 ± 11.65
<b>Aetiology</b>	
IPAH, % (n)	69.5% (16)
CTDPH (systemic sclerosis), % (n)	30.5% (7)
<b>Therapy</b>	
PDE5i, % (n)	60 (14)
Prostanoid, % (n)	13 (3)
Dual PDE5i+ERA, % (n)	26 (6)
<b>Echocardiography</b>	
RV basal diameter, cm	6.9 ± 1.9
LV basal diameter, cm	4.2 ± 1.2
RAA, cm <sup>2</sup>	27 ± 12
TAPSE, mm	20.65 ± 2.96
IVC diameter, mm	21.95 ± 2.12
TRPG, mmHg	40.3 ± 3.9
eRAP, mmHg	27 ± 5.2
AcT, ms	75 ± 21
<b>Hemodynamics (RHC)</b>	
sPAP, mmHg	79.6 ± 30.72
dPAP, mmHg	31.9 ± 13.54
mPAP, mmHg	48.95 ± 18.77
PAWP, mmHg	10.5 ± 2.03
PVR, Wood Units	9.17 ± 5.69
<b>CI, l/min/m<sup>2</sup></b>	2.65 ± 0.60
<b>CVP, mmHg</b>	8.2 ± 2.92
CO <sub>TP</sub> , l/min	4.59 ± 1.05
CI <sub>TP</sub> , l/min/m <sup>2</sup>	2.53 ± 0.54
CO <sub>Fick</sub> , l/min	4.74 ± 1.38
CI <sub>Fick</sub> , l/min/m <sup>2</sup>	2.62 ± 0.65
SVR <sub>RHC</sub> , Wood Units	19.76 ± 4.8

Data are expressed as mean (± standard deviation) except where <sup>#</sup> median [interquartile range].

6MWD – 6-minute walking distance; AcT – acceleration time; BSA – body surface area; CI – cardiac index; CI<sub>Fick</sub> – cardiac index obtained by in-direct Fick's method; CI<sub>TP</sub> – cardiac index obtained by thermodilution method; CO – cardiac output; CO<sub>Fick</sub> – cardiac output obtained by in-direct Fick's method; CO<sub>TP</sub> – cardiac output obtained by thermodilution method; CTDPH – connective tissue disease related pulmonary hypertension; CVP – central venous pressure; dPAP – diastolic pulmonary artery pressure; ERA – endothelin receptor antagonist; eRAP – estimated right atrial pressure; IVC – inferior vena cava; IPAH – idiopathic pulmonary arterial hypertension; mPAP – mean pulmonary artery pressure; PAH – pulmonary arterial hypertension; PAWP – pulmonary artery wedge pressure; PDE5i – phosphodiesterase type 5 inhibitor; PVR – pulmonary vascular resistance; RAA – right atrium area; eRAP – estimated right atrium pressure; RHC – right heart catheterization; sPAP – systemic pulmonary artery pressure; SVR<sub>RHC</sub> – systemic vascular resistance obtained during right heart catheterization; TAPSE – tricuspid annular plane systolic excursion

and related parameters non-invasively. It is also easy to use, cost-effective and allows the continuous measurement of CO at bedside.

Many non-invasive methods for the assessment of CO have been introduced in recent years, with thoracic electrical bioimpedance (TEB) currently being the most popular [11–14]. TEB relates changes in thoracic electrical conductivity to changes in thoracic aortic blood volume and blood flow and has been proposed as a simple and readily reproducible technique for the determination of SV, contractility, CO, SVR, and TFC on a beat-to-beat ba-

**Table 2. Electrical cardiometry parameters**

CO <sub>EC</sub> , l/min	4.86 ± 1.20
CI <sub>EC</sub> , l/min/m <sup>2</sup>	2.70 ± 0.69
SVR <sub>EC</sub> , Wood Units	17.9 ± 4.53
SVV, units	15.08 ± 3.24
ICON, units	45.65 ± 21.53
TFC, units	26.18 ± 5.64

Data are expressed as mean (± standard deviation). CI – cardiac index obtained by electrical cardiometry, CO – cardiac output obtained by electrical cardiometry, ICON – index of contractility, SVR<sub>EC</sub> – systemic vascular resistance obtained by electrical cardiometry, SVV – stroke volume variation, TFC – total fluid capacity

sis [14]. To improve the reliability of impedance measurements, the basic equation was modified substantially by Bernstein and Osypka [15], so that the maximum rate of change of impedance is related to the peak aortic blood acceleration. This method is called electrical velocimetry. This approach is based on the theory that the disc-shaped erythrocytes are aligned in the same direction during the ejection period to achieve minimal flow resistance. The pulsatile alignment of the erythrocytes during early systole and the increasingly random orientation during the course of diastole correspond to a pulsatile increase and decrease in electrical conductivity, which is reflected in a decrease in thoracic electrical bioimpedance during early systole and a later increase [15]. In this new approach to impedance measurements, the main impedance changes are caused by the flow in the aorta. The impedance of tissue that shows a high resistance, such as the lung and the surrounding tissue of the thorax, is not taken into account. Proponents claim that TEB can measure CO with the same clinical accuracy as the thermodilution technique [14,16–17]. Other EC-derived hemodynamic parameters also have shown good correlation with parameters derived via invasive methods.

Recently, the precision of CO obtained by EC was confirmed in study where direction of changes in CO was measured during cardiopulmonary exercise test in patients with dyspnoea. The differences of CO by EC monitor vs CO by indirect Fick method during exercise were within the criteria of acceptability [18].

Also, in other study good agreement between hemodynamic parameters obtained by EC and by invasive methods like RHC and femoral PiCCO catheter was found in group of fifty patients. The percentage errors between EC-CO and RHC-CO or PiCCO-CO were 26.5% and 26.4%, respectively, therefore, EC was admitted as a useful tool for evaluating haemodynamic parameters with clinically acceptable accuracy [19].

EC provides not only insight into afterload monitoring in patients with various cardiovascular disorders, correlation of EC derived TFC with dynamic variations in chest fluid dynamics has made it a useful tool for assessing the clinical necessity of administering diuretic therapy. It was proven that EC parameter, TFC, qualitative parameter of changes in thoracic fluid (calculated as the inverse of the impedance across the thorax), is in good correlation with the amount of fluid added or intended to be used to measure absolute fluid levels. However, dynamic measurements of TFC using EC can reflect directional changes in thoracic fluids, whether increas-

ing or decreasing. It is useful especially in patients undergoing volume shifts, which can include diuretic therapy and haemodialysis [20–22]. Studies have shown that during cardiac surgery total and thoracoabdominal impedances had the highest correlation to fluid balance. Recently Nareula et al. [23] evaluated the effect of autologous blood harvest (ABH)-induced volume shifts using EC in patients with PAH due to left heart disease. They found that EC tracks beat-to-beat fluid and hemodynamic fluctuations during ABH and helps in the execution of an early patient-specific, goal-directed therapy, allowing for its safe implementation in patients with pulmonary hypertension secondary to left heart disease. However, PAH patients develop right sided heart failure with a fluid redistribution and accumulation outside of thorax (peripheral oedema's, ascites, liver enlargement). In our study, TFC did not correlate with any of parameters used to assess PAH patients' fluid management like CVP or IVC diameter.

Also in intensive care units, in a group of patients who underwent cardiac surgery, EC results were in close correlation with obtained by pulmonary artery thermodilution. The difference between methods were within 15% in more than 90% in both hemodynamically stable and unstable patients. Authors claimed that the main limitation of this technique is the lack of cardiac filling pressure determination and this may preclude the replacement of PACs in a substantial proportion of cardiac surgery patients [24].

EC goes a step further in addressing the unmet need for improved methods/devices to measure circulating blood volume and hemodynamic by providing an estimation of dynamic parameters of circulating blood volume or cardiac preload (SVV), afterload (SVR), and cardiac contractility (ICON), thereby assisting in the design of a non-invasive, cost-effectiveness holistic (goal-directed) approach [25].

Main limitations of this pilot study are small patient population and the fact that EC parameters were obtained after RHC at the bedside, outside the cathlab. However, the measurement were performed during normal clinical routine. Disadvantages of EC technique are clinical conditions which can interfere with the accuracy of final results and the device's algorithms do not always detect them e.g. very high/low heart rate (>140/<40 beats per minute), aortic regurgitation, poor electrode skin contact [24].

## Conclusions

Our results confirm that EC could adequately estimate main hemodynamic parameters e.g. CO, CI in comparison with invasive methods in patients with right-sided heart failure. RV hemodynamic parameters are a major determinant of PAH patients' prognosis and survival and EC allows feasible and accurate assessment of CO at the bedside. However, full usefulness of this technique should be validated in further prospective studies with larger number of patients.

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