

Electrical Cardiometry in Patients undergoing Cardiac Catheterisation

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ABSTRACT

Introduction: Reliable noninvasive estimation of haemodynamics may be helpful in decision making in critically ill patients to improve outcome. We have compared the clinical utility of electrical cardiometry (EC) and pulmonary artery catheterisation (PAC) derived parameters in awake, spontaneously breathing patients undergoing percutaneous trans-mitral commissurotomy (PTMC). The parameters compared were cardiac output (CO), stroke volume (SV), systemic vascular resistance (SVR) and their respective indices.

Materials and methods: Prospective observational clinical study was conducted in cardiac catheterisation laboratory of a tertiary hospital in rheumatic heart disease patients ($n = 50$) undergoing PTMC, for comparison of the two techniques. CO and other parameters by EC and PAC were collected simultaneously at T1 (pre-PTMC) and T2 (post-PTMC). Intraclass correlation coefficient (ICC), limits of agreement and mean bias within the data set group and within each patient over time were calculated. Accuracy of CO measured was assessed with Bland-Altman analysis.

Results: EC-CO $3.91 \pm 1.16 \text{ Lmin}^{-1}$ and PAC-CO $3.94 \pm 1.12 \text{ Lmin}^{-1}$ were measured at T1 and EC-CO $4.54 \pm 1.15 \text{ Lmin}^{-1}$ and PAC-CO $4.55 \pm 1.13 \text{ Lmin}^{-1}$ were measured at T2. ICC, mean bias and limits of agreement for CO at T1 were $0.98 - 0.03$ and $- 0.41$ to $+ 0.35$ respectively and T2 were $0.99 - 0.00$ and $- 0.22$ to $+ 0.21$ respectively. Bland-Altman analysis showed a good agreement between EC and PAC derived parameters.

Conclusion: Electrical cardiometry is equivalent to PAC-derived cardiac output in patients undergoing PTMC, provides a novel monitoring technique and a noninvasive, low-cost alternative ideally suited for use during interventional catheter procedures.

Keywords: Non-invasive, Cardiac output, Electric cardiometry, Catheterisation laboratory.

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INTRODUCTION

Reliable haemodynamic measurements help clinicians to make appropriate decisions regarding diagnosis and treatment of critically ill patients. Most commonly used techniques for intra operative cardiac output (CO) estimation are pulmonary arterial thermo dilution technique by Swan et al¹ and by femoral arterial thermo dilution technique Pulse-induced contour cardiac output monitoring.^{2,3} Both

of these techniques based on the Fick's principle measure CO and stroke volume (SV) very precisely, as shown in several comparison studies.²⁻⁵ Controversy however exists regarding the use of pulmonary artery catheters (PAC) in cardiac surgery patients because of its uncertain risk-benefit ratio as the technique requires a central venous access.^{6,7} A large multicentre evaluation did not provide any beneficial impact of the PAC on the prognosis of critically ill patients. The development of safe, simple, non-invasive and cost effective techniques of estimating SV, CO and systemic vascular resistance (SVR) without invasive catheterisation of vessels or intravascular injection of potentially dangerous drug is important for clinical decision-making and research in anaesthesia and critical care medicine.

Recently a number of newer non-invasive methods for assessment of CO have been introduced, and techniques such as impedance cardiography, have become popular.⁸⁻¹⁰ Thoracic electric bioimpedance (TEB) relates changes in thoracic electrical conductivity to changes in thoracic aortic blood volume and blood flow and is a readily reproducible and simple technique for the determination of SV, contractility, CO, SVR, and thoracic fluid content (TFC) on a beat-to-beat basis. Although the technique of measurement of the underlying changes in TEB is technically straightforward, the results of previous studies comparing impedance cardiography with thermo dilution and other methods like transoesophageal echocardiography (TEE) have been largely inconclusive, and led to the conclusion that impedance cardiography produces unreliable and misleading data which may result in inappropriate clinical intervention,¹¹ some investigators have even reported a poor agreement between CO measured by TEB and by the thermo dilution technique in haemodynamically unstable patients and in patients after cardiac surgery with cardiopulmonary bypass (CPB); this discrepancy may result from increased thorax fluid content and subsequently increased conductivity after surgery.¹²⁻¹⁴ By contrast, the newer method called electrical cardiometry (EC) interprets the maximum changes in the TEB as the ohmic equivalent of the mean aortic blood flow acceleration¹⁵ and the various problems with previous models have been overcome by using upgraded computer technology and refined algorithms to calculate CO.¹⁰

Whereas EC previously has been found to produce reliable CO measurements in patients after off pump coronary artery bypass (OPCAB) graft surgery during controlled

ventilation,¹⁶⁻¹⁸ correlation was found to be weak in post OPCAB spontaneously breathing patients.¹⁹ The purpose of our study was to evaluate the efficacy and compare noninvasive CO measurement obtained via EC device (ICON[®]; Osypka Medical, Berlin, Germany) in spontaneously breathing, haemodynamically stable patients, without the influence of any anaesthetic agent compared with invasive measurements obtained via cardiac catheterisation in patients undergoing percutaneous transmitral commissurotomy (PTMC). The clinical parameters compared were cardiac output, stroke volume, systemic vascular resistance and their respective indices.

METHODOLOGY

Study Design

Prospective observational clinical study.

Patient

After institutional ethics committee approval and obtaining written informed consent from the patients, the study was conducted from September 2012 and April 2013 on 50 patients with New York Heart Association (NYHA) classification II/III dyspnoea scheduled to undergo elective cardiac catheterisation and PTMC. The patients were evaluated at the two pre-defined times and generated 100 data triplets which were subsequently analysed.

Patients with haemodynamic instability/on inotropes, need for general anaesthesia, or having peripheral vascular disease suggested by claudication or varicose veins or documented by previous Doppler studies, coagulopathies, age <18 years were excluded from the study.

Cardiac Monitoring

The EC device (ICON[®]; Osypka Medical, Berlin, Germany) was connected and the patient demographic and anthropometric data were entered. Four sensors were applied as follows, first: approximately 5 cm above left base of the neck along the course of the internal carotid artery, second on the left base of neck, third on the lower left thorax at level of xiphoid and the fourth one on the lower left thorax approx 10 to 15 cm below xiphoid on the anterior axillary line.

A balloon tipped, flow-directed PAC (7.5F, Edwards, Irvine, CA) was placed via the femoral vein up to the wedge position and the correct position was confirmed by pressure tracings and radiographically. The femoral artery was cannulated for hemodynamic monitoring and blood samples were obtained for oximetry.

Data Analysis

Cardiac output data triplets were obtained from electric cardiometer at predefined time points: (1) baseline; before

skin puncture for cannulation (2) T2, 5 minutes post procedure and average of three readings was taken for analysis. The CO measurements were collected simultaneously with the two techniques during steady state with an interval of 30 to 60 seconds. None of the measurements was recorded during a haemodynamically unstable phase or during arrhythmias.

Statistics

Reliability of the EC in assessing various haemodynamic parameters in comparison to pulmonary artery catheterisation was assessed using the reliability analysis by calculating the intraclass correlation. Intraclass correlation (ICC) assesses rating reliability by comparing the variability of different ratings of the same subject to the total variation across all ratings and all subjects.

The theoretical formula for the ICC is:

$$ICC = \frac{s^2(b)}{s^2(b) + s^2(w)}$$

where, $s^2(w)$ is the pooled variance within subjects, and $s^2(b)$ is the variance of the trait between subjects. The following ICC values indicated the strength of agreement between the two sets being analysed.

- 0-0.20: Indicates poor agreement
- 0.3-0.4: Indicates fair agreement
- 0.5-0.6: Indicates moderate agreement
- 0.7-0.8: Indicates strong agreement
- >0.8: Indicates almost perfect agreement.

Intraclass correlation has advantages over correlation coefficient, in that it is adjusted for the effects of the scale of measurements, and that it will represent agreements from more than two raters or measuring methods. The ICC was calculated to allow comparison of the results presented here with other studies.

The calculation involves an initial two-way analysis of variance, so a parametric two-way analysis of variance was also conducted. Accuracy of the noninvasive device was defined as the agreement between PAC cardiac output and ICON assessed measurements using the method of Bland and Altman. Bias was defined as the mean difference between cardiac outputs derived from two sites or methods. Limits of agreement were calculated arbitrarily as ± 1.96 SD of the bias.

RESULTS

The study was conducted in 50 adults (males = 25, females = 25) with a mean age of 34.36 ± 10.46 years, body surface area of 1.47 ± 0.14 m² and Haemoglobin of 13.5 ± 2.10 gm/dl. Haemodynamic parameters recorded at baseline and post PTMC are shown in Tables 1 and 2 respectively.

Electrical cardiometry in patients before PTMC/baseline showed a cardiac output of $3.91 \pm 1.16 \text{ Lmin}^{-1}$ which was similar to that shown by cardiac catheterisation $3.94 \pm 1.12 \text{ Lmin}^{-1}$ ($p < 0.05$). The Bland-Altman analysis for EC-CO with cardiac catheterisation (Graph 1A and B, Table 3) at T-1 revealed a mean bias of -0.03 and precision limits of -0.41 to $+0.35 \text{ Lmin}^{-1}$. The ICC coefficient was 0.9856 (Single Rater) and 0.9928 (Average of Raters). Similar analysis at T-2 revealed a EC CO of $4.54 \pm 1.15 \text{ Lmin}^{-1}$ and PAC derived CO of $4.55 \pm 1.13 \text{ Lmin}^{-1}$ ($p\text{-value} < 0.05$), a mean bias of -0.00 and precision limits of -0.22 to $+0.21 \text{ Lmin}^{-1}$ with the ICC coefficient of 0.9953 (Single Rater) and 0.9976 (Average of Raters).

The Bland and Altman analysis was also carried out for rest of the parameters evaluated during the study and showed the results as shown in Table 3.

A small subset of patients ($n = 8$) had dysrhythmias in the form of atrial fibrillation (AF) with controlled ventricular rate. Electrical cardiometry in such patients with dysrhythmias before PTMC showed a CO of $3.65 \pm 0.81 \text{ Lmin}^{-1}$ and patients with normal sinus rhythm had a CO of $3.96 \pm 1.21 \text{ Lmin}^{-1}$ ($p = 0.227$) showing that there was no statistically significant difference in CO estimation in patients with AF by electrical cardiometry in comparison to patients with sinus rhythm. In the post PTMC period EC CO estimation in patients with AF showed a CO of $4.42 \pm 1.19 \text{ Lmin}^{-1}$ and those with sinus rhythm showed a similar CO of $4.57 \pm 1.19 \text{ Lmin}^{-1}$ ($p = 0.225$). Reliability analysis by ICC coefficient was however not performed due to a small population of the subset.

DISCUSSION

Accurate measurements of CO are crucial in the evaluation of patients with valvular heart disease having pulmonary

hypertension and severe heart failure. Impedance cardiography using the TEB has been increasingly explored for its ability to measure CO non-invasively. The thermo dilution (TD) method is an established clinical standard method for evaluation of other CO measurement techniques. This study was performed to investigate whether EC can be used as a complement to, or reliable replacement of TD for CO measurement. The two techniques were compared at baseline and after PTMC. A previous study comparing the effect of ventilation on cardiac output estimation by TEB in comparison to thermodilution concluded a fair correlation between TD CO and TEB CO measurement among post-OPCAB patients during controlled ventilation. However correlation was found to be weak in post OPCAB spontaneously breathing patients.¹⁹ The weak correlation in spontaneously breathing patients in the post-operative period could have resulted from the presence of sternotomy, pleural/mediastinal drain tubes or sternal wires.

The presence of endotracheal tube, mediastinal tubes, pleural tubes, sternal wires and alteration in physiology caused by mechanical ventilation and PEEP, have all been shown to affect the TEB measurements by affecting the rate of change of thoracic impedance.¹²

The trials conducted previously have studied patients undergoing cardiac surgery at various time frames and have thus been influenced by effects of anaesthesia, noxious stimuli like skin incision and sternotomy, cardio pulmonary bypass, use of inotropes or vasodilators or diuretics and presence of pleural and pericardial drains, endotracheal tube and positive pressure ventilation. Our study was thus conducted in spontaneously breathing and un-anaesthetised patients undergoing elective cardiac catheterisation under local anaesthesia to negate these effects. Our study revealed a good correlation between cardiac output measurement by

Table 1: Haemodynamic parameters measured before PTMC using EC and PAC. Values expressed as mean \pm standard deviation

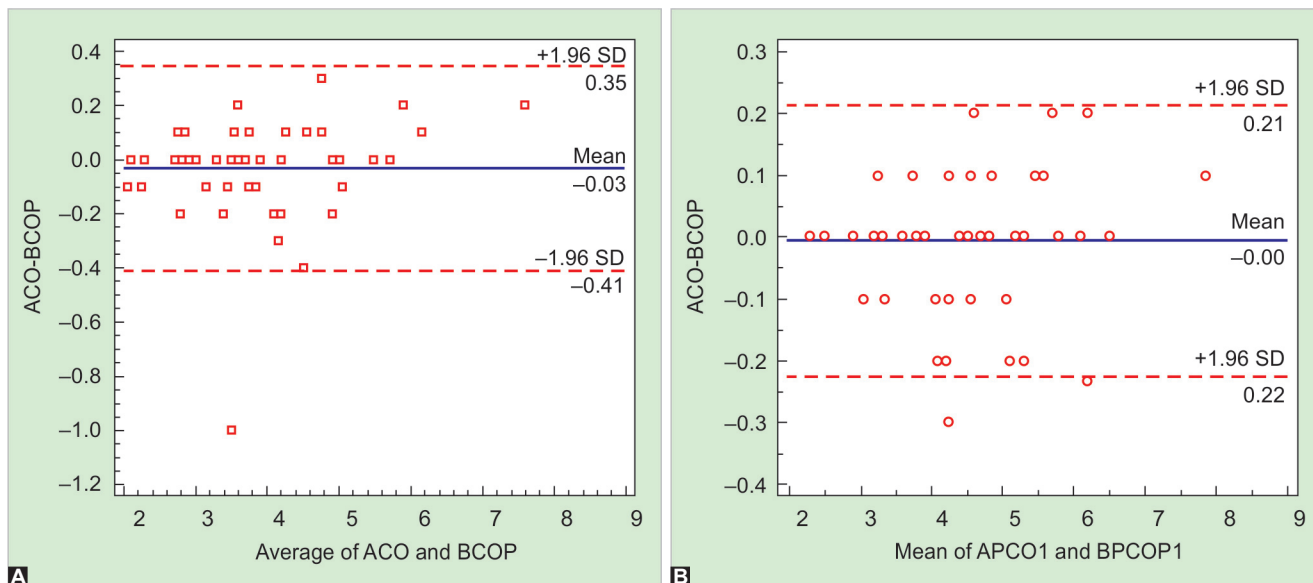
| | EC | PAC | p-value ANOVA | Intraclass correlation |
|--|----------------------|----------------------|---------------|------------------------|
| CO (Lmin^{-1}) | 3.91 ± 1.16 | 3.94 ± 1.12 | <0.05 | 0.98 |
| CI ($\text{Lmin}^{-1}\text{m}^{-2}$) | 2.69 ± 0.79 | 2.69 ± 0.75 | <0.05 | 0.98 |
| SV (mLmin^{-1}) | 46.44 ± 13.17 | 46.39 ± 12.89 | <0.05 | 0.99 |
| SVI ($\text{mLmin}^{-1}\text{m}^{-2}$) | 32.27 ± 9.90 | 31.93 ± 9.12 | <0.05 | 0.98 |
| SVR (dyn.s cm^{-5}) | 1605.12 ± 463.46 | 1600.52 ± 428.84 | <0.05 | 0.97 |
| SVRI ($\text{dyn.s cm}^{-5}\text{m}^{-2}$) | 2303.50 ± 633.70 | 2341.99 ± 632.42 | <0.05 | 0.96 |

Table 2: Haemodynamic parameters measured post-PTMC using EC and PAC. Values expressed as mean \pm standard deviation

| | EC | PAC | p-value ANOVA | Intraclass correlation |
|--|----------------------|----------------------|---------------|------------------------|
| CO (Lmin^{-1}) | 4.54 ± 1.15 | 4.55 ± 1.13 | <0.05 | 0.99 |
| CI ($\text{Lmin}^{-1}\text{m}^{-2}$) | 3.07 ± 0.71 | 3.04 ± 0.72 | <0.05 | 0.98 |
| SV (mLmin^{-1}) | 52.14 ± 14.29 | 52.41 ± 14.16 | <0.05 | 0.99 |
| SVI ($\text{mLmin}^{-1}\text{m}^{-2}$) | 35.21 ± 8.97 | 35.37 ± 9.13 | <0.05 | 0.99 |
| SVR (dyn.s cm^{-5}) | 1307.7 ± 295.82 | 1330.92 ± 287.16 | <0.05 | 0.94 |
| SVRI ($\text{dyn.s cm}^{-5}\text{m}^{-2}$) | 1925.86 ± 447.06 | 1964.03 ± 463.09 | <0.05 | 0.92 |

the two techniques both before and after the procedure with a mean bias of -0.03 and limits of agreement ranging from -0.41 to $+0.35$ $L\text{min}^{-1}$ before the procedure and a mean bias of -0.00 and limits of agreement ranging from -0.22 to $+0.21$ $L\text{min}^{-1}$ after the mitral commissurotomy was done. The ICC coefficient for cardiac output estimation before the procedure was 0.9856 (Single Rater) and 0.9928

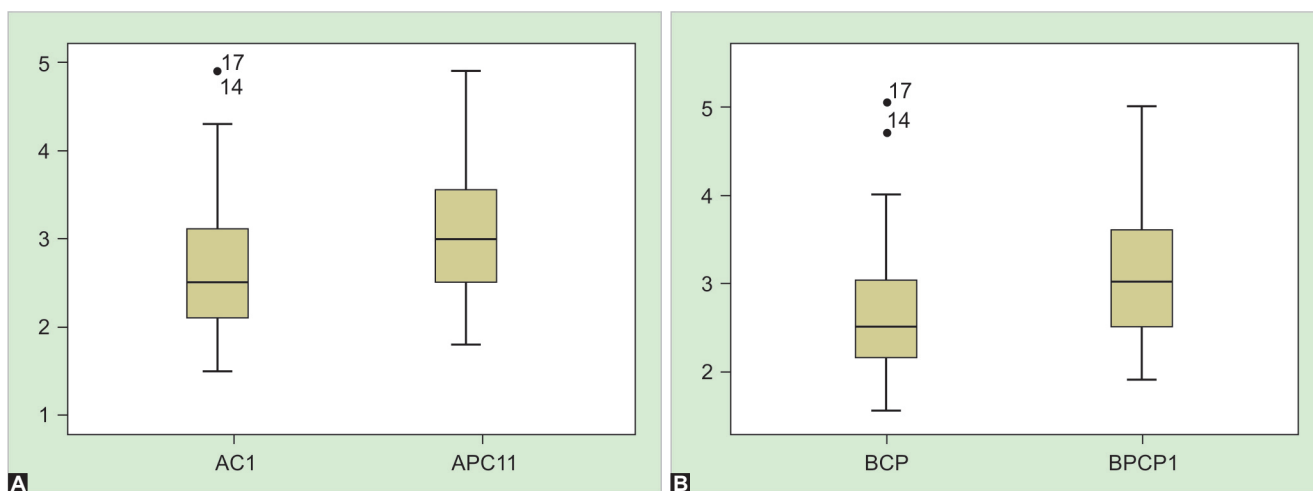
(Average of Raters) and 0.9953 (Single Rater) and 0.9976 (Average of Raters) after the procedure which confirmed an almost perfect agreement between the two techniques. Besides CO, the device also measures stroke volume and systemic vascular resistance as well as their respective values indexed to body surface area of the patient. All these other parameters also were found to be accurately estimated



Graphs 1A and B: (A) The Bland-Altman analysis for EC-CO with cardiac catheterisation at baseline T-1, (B) The Bland-Altman analysis for EC-CO with cardiac catheterisation post-PTMC

Table 3: The Bland-Altman analysis for parameters derived from EC with cardiac catheterisation at baseline and post PTMC

| | Pre procedure | | Post PTMC | |
|----------------|---------------|----------------------|-----------|----------------------|
| | Mean bias | Limits of agreement | Mean bias | Limits of agreement |
| Cardiac output | -0.03 | -0.41 to $+0.35$ | 0.00 | -0.22 to $+0.21$ |
| Cardiac index | 0.00 | -0.33 to $+0.33$ | 0.03 | -0.22 to $+0.28$ |
| Stroke volume | 0.05 | -1.30 to $+1.39$ | -0.3 | -2.7 to $+2.2$ |
| Stroke index | 0.3 | -3.0 to $+3.6$ | -0.2 | -2.7 to $+2.4$ |
| SVR | 4.6 | -197.6 to $+206.8$ | -23.2 | -214.9 to $+168.5$ |
| SVRI | -38.5 | -364.3 to $+287.3$ | -38.2 | -389 to $+312.7$ |



Graphs 2A and B: Cardiac index-increase after PTMC measured by the two techniques, (A) electric cardiometry; (B) pulmonary artery catheterisation

by electric cardiometry as these values when derived from haemodynamic calculations in catheterisation laboratory were found to correlate significantly with those measured non-invasively.

Suttner et al²⁰ reported a good agreement between EC and TD cardiac index measurements in patients after cardiac surgery. Their mean bias was -0.01 ± 0.57 $\text{Lmin}^{-1}\text{m}^{-2}$ in haemodynamically stable patients and 0.03 ± 0.47 $\text{Lmin}^{-1}\text{m}^{-2}$ in haemodynamically unstable patients. Similar results were reported by Gujjar et al,¹⁷ Sageman et al²¹ and Chakravarthy et al²² in post cardiac surgical patients. All of these studies have found TEB technology accurate and interchangeable with TD in post cardiac surgical patients. In our situation in the catheterisation laboratory, patients on inotropes are very critically ill and it will distract everybody if some form of research is being conducted on a critically ill patient and were thus excluded. Additionally a problem of getting consent in our setup was speculated, where patients and their relatives do not want anything new or 'research like' to be tried if the patient has been declared sick or critical.

The cardiac index measured by EC at baseline and after the procedure was 2.69 ± 0.79 $\text{Lmin}^{-1}\text{m}^{-2}$ and 3.07 ± 0.71 $\text{Lmin}^{-1}\text{m}^{-2}$ respectively and by pulmonary artery catheterisation was 2.69 ± 0.75 $\text{Lmin}^{-1}\text{m}^{-2}$ and 3.04 ± 0.72 $\text{Lmin}^{-1}\text{m}^{-2}$ respectively. The pre load was assessed by measuring the central venous pressure and there was no statistically significant change in its values at both the time frames. Cardiac indices measured by the two techniques were found to be not only collaborating at both the time frames but also showed a statistically significant increase at the end of the procedure ($p < 0.05$) (Graph 2A and B). This difference could be due to instantaneous dilatation of the left ventricular inflow following PTMC leading to an increased cardiac output.²³

Sixteen percent ($n = 8$) of the patients who had pre existent arrhythmias EC showed a CO of 3.65 ± 0.81 Lmin^{-1} and 3.96 ± 1.21 Lmin^{-1} in patients with normal sinus rhythm ($p = 0.227$). In the post-PTMC period EC CO estimation in patients with AF showed a CO of 4.42 ± 1.19 Lmin^{-1} and those with sinus rhythm showed a similar CO of 4.57 ± 1.19 Lmin^{-1} ($p = 0.225$). As the cardiac output estimated by the two means showed statistically correlating values, the presence of these dysrhythmias had no impact on estimation of cardiac output by electric cardiometry technique.²⁴ The small but statistically insignificantly decreased CO noted in patients with Atrial Fibrillation might have resulted from the loss of atrial kick in patients with atrial fibrillation.

LIMITATIONS

The technique of electric cardiometry may be sensitive to the placement of the electrodes on the body, variations in

patient body size, and other physical factors that impact on electric conductivity between the electrodes and the skin (e.g. temperature and humidity).^{25,26} The electrodes must stick well, and if patients have oily skin or are diaphoretic, the electrodes may become dislodged. Electrical interference may be encountered during the use of electro-cautery during intra operative usage or from nearby electrical devices being used in the ICU. We however in our study did not face any such issue during our study in the catheterisation laboratory. The other technical drawback of the technology is that it gives an estimate of systemic vascular resistance but no preload measurement. So the physicians would have to estimate preload from other clinical signs/central venous catheterisation, or can test preload adequacy with small fluid challenges. Our study does not inculcate the effects anaesthesia, sternotomy, chest tubes, sternal wires, etc. on cardiac output estimation by electric cardiometry and its accuracy and precision in peri-operative settings cannot be commented upon from our study.

This study has shown that in patients undergoing cardiac catheterisation for percutaneous trans-mitral commissurotomy, EC and PAC are linearly correlated, quantitatively equivalent in mean, track well over time and follow the same pattern of increase post commissurotomy. Electric cardiometry is thus a reliable noninvasive, low-cost alternative to thermo-dilution and pulmonary artery catheterisation derived haemodynamic measurements and is a novel monitoring technique ideally suited for use during interventional catheter procedures. Much work still remains to prove time-tested clinical utility and patient outcome improvement by using EC.

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