Original Article

Comparative Study of Cardiac Output Measurement by Regional Impedance Cardiography and Thermodilution Method in Patients Undergoing off Pump Coronary Artery Bypass Graft Surgery

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ABSTRACT

Background: An ideal CO monitor should be noninvasive, cost effective, reproducible, reliable during various physiological states. Limited literature is available regarding the noninvasive CO monitoring in open chest surgeries.

Aim: The aim of this study was to compare the CO measurement by Regional Impedance Cardiography (RIC) and Thermodilution (TD) method in patients undergoing off pump coronary artery bypass graft surgery (OPCAB).

Settings and Design: We conducted a prospective observational comparative study of CO measurement by the noninvasive RIC method using the NICaS Hemodynamic Navigator system and the gold standard TD method using pulmonary artery catheter in patients undergoing OPCAB. A total of 150 data pair from the two CO monitoring techniques were taken from 15 patients between 40-70 years at various predefined time intervals of the surgery.

Patients and Methods: We have tried to find out the accuracy, precision and cost effectiveness of the newer RIC technique. Mean CO, bias and precision were compared for each pair i.e.TD-CO and RIC-CO as recommended by Bland and Altman. The Sensitivity and specificity of cutoff value to predict change in TD-CO was used to create a Receiver operating characteristic or ROC curve.

Results: Mean TD-CO values were around 4.52 ± 1.09 L/min, while mean RIC- CO values were around 4.77± 1.84 L/min. The difference in CO change was found to be statistically not significant (p value 0.667). The bias was small (-0.25). The Bland Altman plot revealed a mean difference of -0.25 litres. The RIC method had a sensitivity of 55.56 % and specificity of 33.33 % in predicting 15% change in CO of TD method and the total diagnostic accuracy was 46.67%.

Conclusion: A fair correlation was found between the two techniques. The RIC method may be considered as a promising noninvasive, potentially low cost alternative to the TD technique of hemodynamic measurement.

Keywords: Noninvasive cardiac output monitoring, off pump coronary artery bypass graft surgery, regional impedance cardiography, thermodilution

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INTRODUCTION

Cardiac output (CO) is the amount of blood delivered to the tissues by the heart in each minute. CO is the product of heart rate (HR) and stroke volume (SV) where HR denotes heart beats per minute and SV is the amount of blood pumped by the ventricles per beat. An ideal CO monitor should be

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noninvasive, continuous, cost effective, reproducible, reliable during various physiological states and have fast response time. Till date, there is no ideal CO monitor.[1]

Regional Impedance Cardiography (RIC) is based on the principle that the electrical conductance of the blood is higher than that of the surrounding tissue structures. Consequently, with each arterial systolic expansion, an increase in the electrical conductance (or reduction in the electrical resistance) of the body is measured.[2,3] The computer based on mathematical algorithms calculates CO.[4] Two basic technologies of impedance cardiography (ICG) are as follows: the thoracic ICG, where the sensors are placed on the root of the neck and the lower part of the chest, and the whole-body ICG, where four pairs of sensors are used, one pair on each limb or RIC where only two pairs of sensors are used placed on one wrist and contralateral ankle. The most significant advantage of the whole-body ICG in comparison to the thoracic ICG is the use of the peripheral impedance signal for the calculation of the SV. About 75% of the peripheral impedance waveform is borne by the systolic blood volume pulsation of the arterial vasculature of the upper and lower limbs, and the remaining 25% arrive from the trunk.[5,6] While the whole-body ICG peripheral volumetric signal is borne throughout the length of the arterial tree, the thoracic ICG waveform is generated by multiple sources including the aorta, lungs, vena cava, and artifacts due to cardiac movement. As a result, peripheral systolic impedance changes are more reliable than the thoracic impedance changes for calculating the SV.[7] Also, the presence of endotracheal tube, mediastinal and pleural tubes, sternal wires, and alteration in physiology caused by mechanical ventilation and PEEP have shown to affect the thoracic electrical bioimpedance (TEB)@ measurements by affecting the rate of change of thoracic impedance.[8]

CO in our study was also simultaneously measured using the NICaS hemodynamic navigator system. It is the only method of ICG that utilizes dual-impedance electrodes, placed on two limbs, preferably one on the wrist and the other on the contralateral ankle.

CO measurement using TEB has been studied in the postoperative period, cardiac catheterization labs, and especially in intensive care units.[8-19] Very few clinical trials have been conducted for monitoring CO using ICG or RIC in particular in open chest cardiac surgery.[20,21] Hence, in this study, we have evaluated CO measurement, the accuracy, precision, and cost effectiveness of RIC using NICaS and compared it with the gold standard thermodilution (TD) method by pulmonary artery catheter (PAC) in patients undergoing off pump coronary artery bypass grafting (OPCAB).

MATERIALS AND METHODS

A prospective, observational, single center study was conducted between December 2018 and March 2020, after obtaining approval from the institutional review board. Three hundred observations from 15 subjects of 40–70 years age group, undergoing elective OPCAB surgery, with New York Heart Association (NYHA) classification II/III status, were included in the study. Patients undergoing emergency surgery and those having signs of congestive heart failure, congenital heart defects, significant arrhythmias, LVEF of <30%, valvular dysfunction, intracardiac shunt, hemodynamic instability (HR >120 beats/min, systolic BP <90 mmHg and/or mean arterial pressure <60 mmHg, and urine output <0.5 mL/kg/h), and on intraoaortic balloon pump support or a pacemaker or undergoing any combined procedure were excluded from the study.

A routine preanesthetic check was done. Chest radiograph, electrocardiogram, and echocardiography were performed to rule out the presence of any valvular or congenital heart defects, low ejection fractions, and arrhythmias. Height and weight were noted for each subject. A written informed consent was taken from each patient a day prior to surgery. Patients were kept nil orally for 6–8 h prior to induction of general anesthesia.

Standard anesthesia protocol, consisting of midazolam 0.05 mg/kg, fentanyl citrate 5 mcg/kg, thiopentone sodium 5 mg/kg, vecuronium bromide 0.1 mg/kg, and isoflurane, was used for all the patients. Routine cardiac monitoring, including the use of PAC, was employed. CO was determined by the TD method. Ten milliliters of cold saline was injected into the proximal injectate port of flow-directed PAC (Edwards Lifesciences, Irvine, USA) within 3 s. CO was also measured by the RIC method by NICaS hemodynamic navigator system (Sandor Medicaids Pvt. Ltd., Hyderabad, India). NICaS is a tetrapolar apparatus that transmits a small electrical signal (1.4 mA @ 30 kHz) through the body through two sensors arranged in a wrist-to-ankle configuration. With each heartbeat, the volume of blood in the arterial system changes and this results in change in the body's electrical resistance. The analog resistance signals are received by the device, where they are amplified and filtered. These signals are then transmitted to a microprocessor, where they are analyzed via mathematical algorithms [Figure 1]. Dual impedance electrodes were placed on the two wrists of the patient since the ankle had to be used for saphenous vein harvesting [Figure 2].

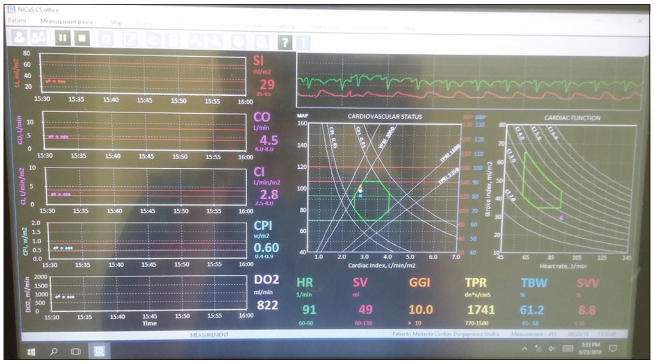

Figure 1: NICaS standard screen

Figure 2: Placement of NICaS electrodes

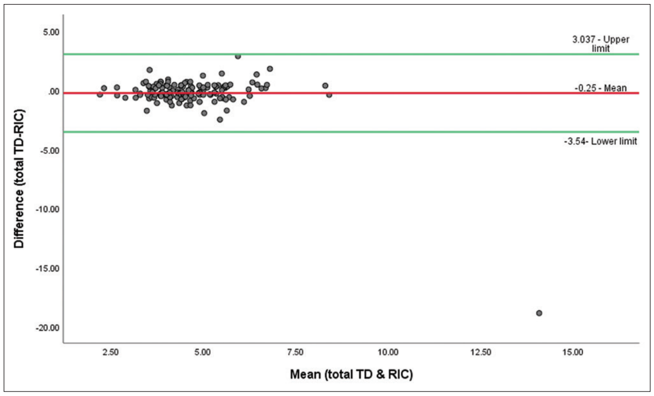

Figure 3: Bland–Altman plot of total time periods for TD and RIC methods

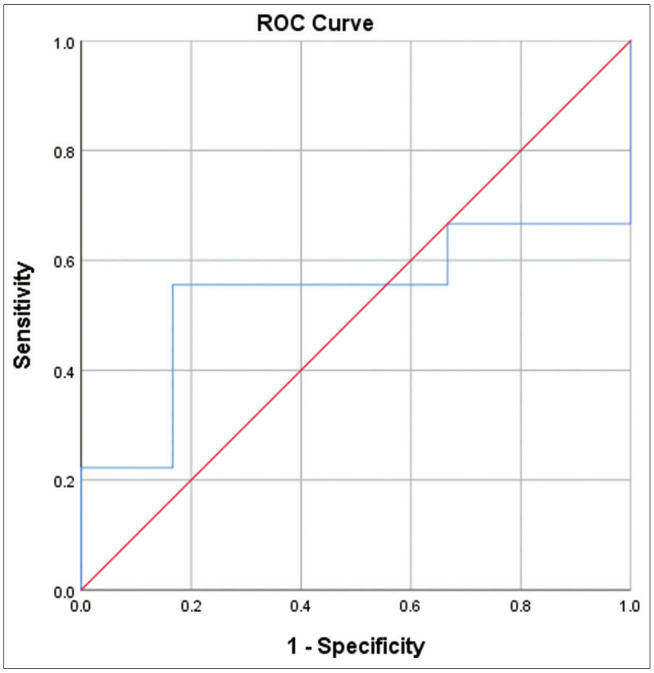

Figure 4: Predictive validity of RIC method In Predicting 15% change in CO of TD method (ROC analysis)

Test Result Variable (s): RIC method CO

Area under the curve	Std. error	95% C.I. of AUC		*P*
		Lower bound	Upper bound	
0.537	0.156	0.231	0.843	0.814

For the purpose of study, the measurements were taken both intraoperatively and postoperatively in the ICU after the patients were stabilized and warmed up to a core temperature of 36°C.

In the intraoperative period, the double CO data were obtained, one from electric cardiometry site and second from the PAC at same point of time and at five predefined time intervals:

T1 - 5 min after anesthetic induction when arterial cannula and PAC will be the *in situ* and electric cardiometry electrode been placed.

T2 - 5 min after sternotomy

T3 - during distal coronary grafting

T4 - 5 min after protamine administration

T5 - 5 min after sternal closure

Postoperatively, all the patients were electively ventilated and were subsequently weaned off the ventilator as per the institutional guidelines. In the postoperative ICU period, the readings were recorded at 4 h intervals till the PAC was out until 48 h of surgery.

Almost 150 data pairs of CO were estimated to be taken for the comparative study purpose.

Sample size calculation-

The formula used is as under:

$$n = (\sigma_1^2 + \sigma_2^2)(Z_\alpha + Z_\beta)^{2/}(m_1 - m_2)^2$$

where

σ = standard deviation

Z_α = value of standard normal variate corresponding to α level of significance

Z_β = the standard normal deviate for desired power

m = average

Sample size was based on a study conducted in 1998 by *Genoni et al.*[22]

On the basis of literature review by Sharma *et al.*,[4] it was estimated that to recognize a clinically significant CO difference of 300 mL/min between the two methods with a power of 0.80, at least 140 paired samples are required to be compared. In the study, there were 10 paired observations for each patient. In view of this, a sample of 15 patients was considered to be adequate for the study.

Statistics

Descriptive analysis was carried out by mean and SD for quantitative variables, frequency, and proportion for categorical variables. Normally distributed continuous parameters were compared between two methods using independent sample *t*-test. Sensitivity, specificity, diagnostic accuracy, true positive, true negative, etc., were determined using the Chi-square test results. Precision was determined by coefficient of error and coefficient of variation (CV).[23] *P*-value < 0.05 was considered as statistically significant. IBM SPSS version 22 was used for statistical analysis*.

Table 1: Demographic data

Demographic variables	Patients selected (mean±SD)
Age (in years)	56±14
Weight (in kg)	75±22
Height (in cm)	165±13
Gender (male: female)	13 : 2

*IBM Corp. Released 2013. IBM SPSS Statistics for Windows, Version 22.0. Armonk, NY: IBM Corp.

Mean CO, bias (mean difference between the CO from the paired values), and precision (±2 SD of the average of biases) were compared for each pair as recommended by Bland and Altman. Limits of agreement were calculated arbitrarily as ± 1.96 SD of the bias. Percentage error (ratio of precision to mean CO of the two methods, i.e., 1.96 SD/mean CO) to determine acceptable limits of agreement between both techniques of CO measurement were calculated using the formula given by Critchley and Critchley.[23] Precision = 2×CV, where CV = SD/mean, for repeated measurements Precision = 2×CE, where CE = CV/$\sqrt{n}$.

We used ROC – receiver operating characteristic curve analysis to better illustrate the trending capability of RIC-CO. The change in RIC-CO needed to predict an acute change in CO larger than 15% of TD-CO was tested. The sensitivity and specificity of cutoff value to predict change in TD-CO was used to create a ROC curve analysis with a cutoff value of 15%.

Table 2: Comparison of TD-CO and RIC-CO

Time point	TD Mean±SD	RIC Mean±SD	Percentage error	Bias	Limits of agreement	*P*
5 min postinduction – T1	3.83±0.92	4.17±1.08	8.88	-0.3387	-1.57 to 0.89	0.362
5 min poststernotomy – T2	4.33±0.98	4.5±0.79	3.93	-0.1713	-1.01 to 0.67	0.603
During distal coronary grafting – T3	4.03±1.42	5.38±5.22	33.50	-1.348	-10.88 to 8.18	0.342
5 min postprotamine – T4	5.05±1.47	5.03±1.32	0.40	0.0173	-1.24 to 1.28	0.973
5 min poststernal closure – T5	5.07±1.07	4.97±0.86	1.97	0.104	-1.84 to 2.05	0.772
At 1 h of shifting the patient to ICU –T6	4.74±0.78	4.74±0.87	0.00	0.0007	-0.89 to 0.89	0.998
Every 4 h interval – T7	4.53±0.89	4.92±0.93	8.61	-0.392	-1.46 to 0.67	0.248
Every 4 h interval – T8	4.57±1.13	4.63±0.93	1.31	-0.0607	-1.76 to 1.64	0.874
Every 4 h interval – T9	4.35±0.86	4.66±0.91	7.13	-0.3067	-2.28 to 1.67	0.353
Every 4 h interval – T10	4.69±0.81	4.7±0.58	0.21	-0.0047	-1.15 to 1.14	0.986
Mean (average of total)	4.52±1.09	4.77±1.84	8.88	-0.25	-3.54 to 3.04	0.154

Table 3: Comparing the precision of TD and RIC method

Time point	Percentage error	TD Precision	RIC Precision
5 min postinduction – T1	8.88	0.480	0.518
5 min poststernotomy – T2	3.93	0.453	0.351
during distal coronary grafting – T3	33.50	0.705	1.941
5 mins postprotamine – T4	0.40	0.582	0.525
5 min poststernal closure – T5	1.97	0.422	0.346
at 1 h of shifting the patient To ICU – T6	0.00	0.329	0.367
every 4-h interval – T7	8.61	0.393	0.378
every 4-h interval – T8	1.31	0.495	0.402
every 4-h interval – T9	7.13	0.395	0.391
every 4-h interval – T10	0.21	0.345	0.247
Mean (average of total)	8.88	0.153	0.488

RESULTS

A total of 15 patients of NYHA II and III, physical status between age 40 and 70 years undergoing elective OPCAB surgery, were selected [Table1]. CO was measured using standard TD technique using PAC and RIC methods.

Comparing TD with RIC method during transition at mean (average of total), the analysis showed that the bias (-0.25) between TD and RIC method was small, the limits of agreement were broad [Table 2].

The precision of mean (average of total) in TD group was 0.153 and it was 0.488 in RIC group. As a conclusion, at the time point T3, Bias was very small and percentage error was heavy with good precision for both the methods with 0.71 in TD method and 1.94 in RIC method. At the time of point T5 percentage error was nil with almost same precision for both the methods [Table 3] [Figure3].

Among the study population, 6 (40%) participants T1–T10 difference was less than 15% and 9 (60%) participants T1–T10 difference was more than or equal to 15% [Table 4] [Figure4].

The RIC method had failed predictive validity in predicting change in CO in the TD method, as indicated by area under the curve of 0.537 (95% C.I. 0.231–0.843, *P*-value 0.814).

Out of six participants, the TD method with CO change less than 15%, four (66.67%) participants CO in RIC were more than 0.51 and two (33.33%) participants were less than or equal to 0.5. Out of nine participants, the TD method with CO change more than or equal 15%, five (55.56%) participants CO in RIC was more than 0.51 and four (44.44%) participants RIC was less than or equal to 0.5. The difference in proportion of the TD method CO change between CO in RIC was statistically not significant (*P*-value 0.667) [Table 5].

Table 4: Descriptive analysis of T1–T10 Change (%)

T1–T10 Difference (%)	Frequency	Percentages
<15	6	40.00
≥15	9	60.00

Table 5: Comparison of 15% change in CO of TD method with RIC CO

RIC cardiac output	TD method CO change %		Chi-square	*P*
	<15 (*n*=6)	≥15 (*n*=9)		
> 0.51	4 (66.67%)	5 (55.56%)	0.185	0.667
≤ 0.51	2 (33.33%)	4 (44.44%)		

The RIC method had a sensitivity of 55.56% (95% CI: 21.2– 86.3%) in predicting 15% change in CO of the TD method. Specificity was 33.33% (95% CI: 4.33– 77.72%), false-positive rate was 66.67% (95% CI: 22.28– 95.67%), false-negative rate was 44.44% (95% CI: 13.7– 78.8%), positive predictive value was 55.56% (95% CI: 21.2– 86.3%), negative predictive value was 33.33% (95% CI:. 4.33– 77.72%), and the total diagnostic accuracy was 46.67% (95% CI: 21.27– 73.41%) [Table 6].

The newer method of CO monitoring by RIC was found to be cheaper as compared to the TD technique [Table 7].

DISCUSSION

In the modern world, there is a strong urge toward development of minimally invasive or noninvasive test for measuring cardiac physiologic parameters which is cost effective, reproducible, and reliable during various physiological states and has a fast response time.

We have conducted a prospective comparative study of CO measurement by RIC and TD methods in patients undergoing OPCAB and have tried to find out the accuracy, precision, and cost effectiveness of the newer method of CO monitoring – the RIC technique. In our study, we have included a total of 15 patients of NYHA II/III physical status between age 40 and 70 years of similar demographic variables like mean weight, height, body mass index, and gender undergoing OPCAB surgery.

Main observation was that the bias between TD and RIC methods was small (-0.25), the limits of agreement were broad. The Bland–Altman plot revealed a mean difference of -0.25 L. The RIC method had failed predictive validity in predicting change in CO by the TD method (by ROC analysis, area under the curve being 0.537). Also, the

Table 6: Predictive validity of RIC method in predicting 15% change in CO of TD method

Parameter	Value	95% CI	
		Lower	Upper
Sensitivity	55.56%	21.20%	86.30%
Specificity	33.33%	4.33%	77.72%
False-positive rate	66.67%	22.28%	95.67%
False-negative rate	44.44%	13.70%	78.80%
Positive predictive value	55.56%	21.20%	86.30%
Negative predictive value	33.33%	4.33%	77.72%
Diagnostic accuracy	46.67%	21.27%	73.41%
Positive likelihood ratio	0.83	0.31	3.204
Negative likelihood ratio	1.33	0.03	5.127

Table 7: Comparing the cost of the two devices

	TD (PAC)	RIC – a pair of electrodes
Cost per patient	Rs 5000-7000	Rs 2000-3000

difference in proportion of the TD method CO change between CO in RIC was statistically not significant (*P*-value 0.667). The RIC method had a sensitivity of 55.56% and a specificity of 33.33% in predicting 15% change in CO of the TD method, and the total diagnostic accuracy was 46.67%.

Our results corroborated with the study by *Rajput et al.*,[20] who compared the CO measurement by the noninvasive method with Electrical Cardiometry and invasive Method with TD technique in 25 patients undergoing CABG. A total of 150 double data of CO were compared with TD-CO and TEB-CO. The TDCO value ranges from 1.8 to 6.9 L/min with a mean of 4.39 ± 1.16 L/min and TEBCO ranges from 1.8 to 7.1 L/min with a mean of 4.21 ± 1.16 L/min.

Our results were similar to a study by *Sharma et al.,*[4] where a total of 230 data pairs of CO were obtained. During controlled ventilation, TD CO values ranged from 2.29 to 6.74 L/min, while TEB CO values ranged from 1.70 to 6.90 L/min. In spontaneously breathing patients, TD CO values ranged from 2.66 to 6.92 L/min, while TEB CO values ranged from 3.08 to 6.90 L/min. A fair correlation was found between TD CO and TEB CO measurements among post-OPCAB patients during controlled ventilation. However, the correlation was weak in spontaneously breathing patients.

Tonelli et al.[18] had a similar conclusion. The CO (mean ± SD) by TD and by ICG was 5.9 ± 2.2 and 5.6 ± 1.5 L/min, respectively.

Gujjar et al.[19] did not found any different result. The mean TEB-CO was 5.15 ± 1.27 L/min, and TD-CO was 5.22 ± 1.28 L/min.

Spiess et al.[21] also found that the CI by TEB and TD-PAC had an overall correlation of $r = 0.71$ ($P < 0.0001$). The Bland–Altman statistics showed a mean difference of − 0.28 L/min/m^2 and a precision of 0.67 L/min/m^2.

Our results were somewhat different from those reported by *Spiering et al.*[24] who conducted a study to assess the degree of agreement between ICG, using the NCCOM3-R7 device, and the TD method—both under basal conditions and after stimulation of CO by dopamine. Thirty-five paired measurements were taken in five healthy male volunteers. During dopamine infusion dye dilution CO was 7.7 (1.8) L/min v 10.5 (3.6) L/min for the NCCOM3-R7 ($P < 0.001$). They speculated about the reasons why ICG fared so badly. The *Sramek–Bernstein approach by Thomas*[25] that they used probably caused specific problems, as they found the correlation between TD and ICG according to *Kubicek et al.*[26] to be much better.

Poorcorrelation was found with the study conducted by *Preiser et al.*[27], where eight patients were studied (six men, two women), among them six were postcardiac surgery patients and two were postoesophagogastrectomy patients. Each of them was mechanically ventilated. CO was lower with TEB than with TD (3.97 + 0.80 vs 4.83 _+ 1.16 L/min $P = 0.004$), and there was poor correlation between the values ($r = 0.41$). This may be due to the assumptions that were made by them while computing CO by TEB such as measurement of aortic blood flow depends on blood specific resistivity, which can vary with hematocrit and other factors, the TEB method regards thorax as being a perfect cylinder and assumes a fixed relationship between the length and radius of the cylinder, and that the perfusion within the thorax is homogeneous and the distribution of blood flow is largely influenced by the cardiovascular status of the patient.

Limited literature is available regarding the intraoperative noninvasive CO monitoring by the RIC (peripheral impedance) method. We have tried to compare it with the gold standard TD method. Our study corroborated with quite a lot of studies available, thus adding to the literature about the reliability of RIC in CO monitoring.

However, there are a few limitations to this study. Our study had enrolled a small number of patients as the machine for RIC was available at our center for a limited time period due to logistic reasons. However, we took 300 observations to arrive at a conclusion. A relatively smaller number of female patients (2 vs 13 male patients) was again a limitation, considering the fact that gender is one of the important patient characteristics in the computation of CO. We attempted to minimize all possible controllable sources of error while measuring CO. Sources of errors in the RIC method include incorrect electrode placement, use of electrocautery while taking measurements. Small alterations in the position of the sensing inner electrodes produce changes in CO of 5–10%; decreased distance leads to overestimation, whereas increasing distance produces underestimation of CO. Incorrect input of height and weight of the patient in the computerized system has similar effects. All RIC measurements were performed by the same investigator, who had been trained by the manufacturer on proper placement of electrodes and use of the machine. Knowledge of the impedance waveform morphology is important because waves that appear unreal may generate erroneous data. Therapeutic interventions based on CO values and calculated hemodynamic parameters in patients with poor ejection fraction are considered as one of the indications for the use of PAC. A comparison with RIC in this patient population is also needed, though not undertaken in the present study. Thus, it would be interesting to evaluate the newer technique in these patients.

In conclusion, we found a high concordance among the 150 paired CO values measured by TD and RIC across 15 patients. RIC may be considered as a promising noninvasive, potentially low-cost alternative to the TD technique of hemodynamic measurement. However a large multicentric randomized controlled trial on varied patient categories may be needed to further validate the obtained results. Although much work remains to prove time-tested clinical utility and patient outcome improvement by using RIC, we believe that this technology shows a great deal of promise.

Declaration of patient consent

The authors certify that they have obtained all appropriate patient consent forms. In the form, the patient (s) has/have given his/her/their consent for his/her/their images and other clinical information to be reported in the journal. The patients understand that their names and initials will not be published and due efforts will be made to conceal their identity, but anonymity cannot be guaranteed.

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Conflicts of interest

There are no conflicts of interest.

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