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ORIGINAL RESEARCH

Cardiac output measurement in liver transplantation patients using pulmonary and transpulmonary thermodilution: a comparative study

Luigi Vetrugno[1] · Elena Bignami[2] · Federico Barbariol[3] · Nicola Langiano[1] · Francesco De Lorenzo[1] · Carola Matellon[3] · Giuseppe Menegoz[4] · Giorgio Della Rocca[1]

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Abstract

During liver transplantation surgery, the pulmonary artery catheter—despite its invasiveness—remains the gold standard for measuring cardiac output. However, the new EV1000 transpulmonary thermodilution calibration technique was recently introduced into the market by Edwards LifeSciences. We designed a single-center prospective observational study to determine if these two techniques for measuring cardiac output are interchangeable in this group of patients. Patients were monitored with both pulmonary artery catheter and the EV1000 system. Simultaneous intermittent cardiac output measurements were collected at predefined steps: after induction of anesthesia (T1), during the anhepatic phase (T2), after liver reperfusion (T3), and at the end of the surgery (T4). The 4-quadrant and polar plot techniques were used to assess trending ability between the two methods. We enrolled 49 patients who underwent orthotopic liver transplantation surgery. We analyzed a total of 588 paired measurements. The mean bias between pulmonary artery catheter and the EV1000 system was 0.35 L/min with 95% limits of agreement of − 2.30 to 3.01 L/min, and an overall percentage error of 35%. The concordance rate between the two techniques in 4-quadrant plot analysis was 65% overall. The concordance rate of the polar plot showed an overall value of 83% for all pairs. In the present study, in liver transplantation patients we found that intermittent cardiac output monitoring with EV1000 system showed a percentage error compared with pulmonary artery catheter in the acceptable threshold of 45%. On the others hand, our results showed a questionable trending ability between the two techniques.

Keywords Anesthesia · Cardiac output monitoring · Liver transplantation · Thermodilution

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✉ Luigi Vetrugno
luigi.vetrugno@asuiud.sanita.fvg.it

Elena Bignami
elenagiovanna.bignami@unipr.it

Federico Barbariol
fedefedoz@gmail.com

Nicola Langiano
niklang2001@yahoo.it

Francesco De Lorenzo
frdelorenzo@libero.it

Carola Matellon
carola.matellon@yahoo.it

Giuseppe Menegoz
gmenegoz@gmail.com

Giorgio Della Rocca
giorgio.dellarocca@uniud.it

[1] Anesthesiology and Intensive Care Clinic, Department of Medicine, University of Udine, P.le S. Maria della Misericordia n.15, 33100 Udine, Italy

[2] Anesthesiology, Critical Care and Pain Medicine Division, Department of Medicine and Surgery, University of Parma, Viale Gramsci 14, 43126 Parma, Italy

[3] Anesthesiology and Intensive Care 1, University-Hospital of Udine, P.le S. Maria della Misericordia n.15, 33100 Udine, Italy

[4] Statistical Physics, SISSA, University of Trieste, via Bonomea 265, 34136 Trieste, Italy

1 Introduction

The gold standard method for measuring cardiac output (CO) during liver transplantation surgery is the pulmonary artery catheter (PAC) [1]. However, experts agree that transesophageal echocardiography (TEE) is also useful for managing rapid hemodynamic changes in this type of surgery; and this two device—PAC and TEE—appears to be the most widely used worldwide [2]. The hemodynamic status of these patients is complex and may include cirrhotic cardiomyopathy, vascular tone abnormalities, microvascular dysfunction, acute cardiovascular failure, and sudden changes of preload during the most turbulent surgical phases of the transplant [3, 4]. Some anesthesiologists consider the Model for End-State Liver Disease (MELD) score regarding whether or not to use the PAC catheter, since higher MELD scores are associated with increased bleeding risk and decreased survival rates [5]. That said, the most frequent criticism of the use of PAC is its invasiveness [6]. Thus, the use of PAC can come at a price when inserting the catheter through the heart into the pulmonary artery to measure pulmonary thermodilution intermittent cardiac output (PT-iCO) or semi-continuous cardiac output. Today, the available less invasive calibration alternatives are the PiCCO® (Pulsion Medical Systems, Munich, Germany) and the most recent EV1000/VolumeView™ (Edwards LifeSciences, Irvine, CA, USA). Both techniques allow transpulmonary thermodilution intermittent cardiac output (TPTD-iCO) and continuous cardiac output (TPTD-CCO) measurements using only a central venous line and an arterial catheter [7]. Until now, however, the new EV1000 system has been evaluated only in an animal model [8] and in critically ill patients [9], thus requiring validation in the operating room with hemodynamically unstable patients.

The first aim of this study was to assess the agreement in measuring iCO between PAC and EV 1000 in patient undergoing liver transplantation. The second aim of this study was to analyze the correlation and concordance coefficients and trending abilities between these two techniques measuring PT-iCO and TPTD-iCO during surgery.

2 Methods

2.1 Study design

This was an observational, prospective, single-center study on adult patients undergoing liver transplantation surgery at the University Hospital of Udine, Italy. The Institutional Review Board of Friuli-Venezia-Giulia approved the study protocol (#21013) before the enrollment of the first patient. Written informed consent was obtained from all participants. They were informed that they could decline to participate at any time. Exclusion criteria were: lack of the consent, combined kidney–liver transplant, acute on chronic liver failure, and moderate peripheral vascular disease. The following demographic data were obtained for each patient: age, gender, weight, height, and body surface area (BSA). In the operating room, after anesthesia induction and trachea intubation, right radial artery cannulation was performed, followed by the positioning of an internal jugular vein 8.5-Fr introducer (AVA 3Xi 8.5-Fr, Edwards Lifesciences, Irvine, CA) through which a PAC catheter was inserted (Swan-Ganz CCOmbo V CCO/SvO_2%CEDV/VIP, Edwards Lifesciences). A PAC catheter was then connected to a Vigilance™ hemodynamic monitor (Edwards Lifesciences) for semi-continuous and PT-iCO measurements. At the same time, a second operator (senior resident) placed a 5-Fr introducer into the femoral artery, through which a 4-Fr VolumeView catheter (Edwards Lifesciences) was inserted and connected to the EV1000 system for TPTD-iCO and TPTD-CCO measurements. Major vascular cannulations were always performed under ultrasound guidance.

2.2 Study protocol

During surgery, almost simultaneous measurements of PT-iCO with PAC and TPTD-iCO with EV1000 were collected at the following time intervals: after induction of anesthesia (T1), during anhepatic phase (T2), after liver reperfusion (T3), and at the end of the surgery (T4). For both PT-iCO and TPTD-iCO, three consecutive boluses were injected without regard to the phase of the respiratory cycle over a 2-min period. PT-iCO measurements were assessed by injecting 10 mL of saline through the PAC, while TPTD-iCO measurements were assessed by injecting 20 mL of cold isotonic saline (< 15 °C) through the central venous catheter. In case of a discrepancy in iCO value greater than 15%, five measurements were done for each device, and the lowest and the highest results were discarded. The injections were always performed by the same investigator. As stated by their manufacturers, the Stewart–Hamilton equation was used for both the PAC and the EV1000 systems to calculate iCO. Although both techniques provide continuous cardiac output (CCO) parameters (the EV 1000 through a calibrated pulse contour analysis), we did not record nor studied these variables. This is due to the fact that the reliability of CCO is very doubtful during periods of hemodynamic instability and sudden changes of volemia, requiring frequent recalibration with saline boluses.

2.3 Surgical technique

In our center and for the study protocol, surgeons used the modified "piggyback" technique introduced at the end of the 1990s by Tzakis et al. [10, 11], consisting of preserving the full length of the recipient's vena cava but with anastomoses of the donor suprahepatic veins to the ostium of the recipient's left and middle suprahepatic veins without need for a venovenous bypass.

2.4 Statistical analysis

Descriptive statistic was calculated employing mean and standard deviation for quantitative variables and the absolute and relative frequencies for qualitative variables. The two thermodilution techniques (pulmonary and transpulmonary) were compared using the analysis described by Bland and Altman, modified with multiple measurements per subject and with the true value constant in each subject [12, 13]. Bias is the mean difference between the two methods and represents the systematic error (that is, the accuracy); precision is represented by the standard deviation of the bias. The upper and lower limits of agreement (LoA) are defined as the range in which 95% of the differences between the two methods are expected to rest (mean bias ± 2 SDs) [14]. As correlation indices, we performed both Spearman's rank correlation and concordance correlation coefficient analysis (CCC) to check whether or not their results were comparable, as their differences (or lack thereof) provide additional information. To assess trending ability we employed 4-quadrant and polar plot techniques to visualize changes in iCO, obtained subtracting consecutive measurements and excluding statistical noise corresponding to changes smaller than 0.5 L/min. "Concordance rate" is defined as the fraction of points lying in the odd quadrants of the 4-quadrant plot [15]. Correspondingly, the "angular concordance rate" for polar plot is defined as the fraction of points with angular distance to the x-axis smaller than 30° [16]. Statistical analyses were performed using MedCalc for Windows, version 16.8 (MedCalc Software, Ostend, Belgium) and R version 3.2.5 for Linux (R Foundation, Vienna, Austria).

3 Results

3.1 Descriptive data analysis

We enrolled 49 patients who were scheduled to undergo orthotopic liver transplantation surgery between November 2012 and October 2015. Patients' demographic data, MELD scores, underlying diseases, and main comorbidities are shown in Table 1.

Table 1 Patients' demographic data, MELD score, underlying and coexisting diseases

	Mean ± SD
Patient numbers	49
Age (years)	56 ± 8
Men/women	31/18
Weight (kg)	71.8 ± 10.8
Height (cm)	168 ± 8
MELD score	17 ± 6
< 10	2 (4)
10–19	35 (71.5)
20–29	10 (20.5)
≥ 30	2 (4)
Underlying disease	
HBV/HCV-related HCC with cirrhosis	15 (31)
HBV cirrhosis	3 (6)
HCV cirrhosis	6 (12)
Alcoholic cirrhosis	15 (31)
Cryptogenetic cirrhosis	1 (2)
Autoimmune cirrhosis	4 (8)
HCV + alcoholic cirrhosis	4 (8)
Echinococcus	1 (2)
Coexisting diseases	
Obesity	8 (16)
Chronic obstruction pulmonary disease	6 (12)
Hypertension	10 (20)
Diabetes mellitus	7 (14)
Coronary artery disease	1 (2)
Hepatorenal syndrome	9 (18)

Percentage is reported as % in parentheses

MELD Model for End-State Liver Disease score, *HBV* Hepatitis B virus, *HCV* Hepatitis C virus, *HCC* hepato-cellular carcinoma

3.2 Hemodynamic data

Cardiac output measurements for all enrolled patients were analyzed for a total of 588 paired measurements (147 data sets for each phase). Measurements derived from the two methods at the various time points are reported in Table 2. The overall mean PT-iCO was 7.5 ± 2.5 L/min, which was slightly higher than the overall mean TPTD-iCO, 7.2 ± 2.3 L/min ($p < 0.001$). For each surgical phase, the results of Bland–Altman analysis (corrected for multiple observations per individual), and correlation coefficients are shown in Fig. 1 and Table 2. We found an overall bias of 0.35 L/min with 95% limits of agreement of −2.30 to 3.01 L/min and an overall percentage error of 35%. Correlation coefficients were found to be relatively substantial at all stages;

Table 2 Mean difference among PT-iCO and TPTD-iCO, precision (SD ± bias), lower and upper LoA together with 95% confidence intervals (bias ± 2 SD), mean percentage error, Spearman's rho, concordance correlation coefficient, precision, accuracy, angular bias and SD for angular bias at predefined step

	Basal (T1)		Anhepatic (T2)		Reperfusion (T3)		End (T4)		Total	
	PT	TPTD	PT	TPTD	PT	TPTD	PT	TPTD	PT	TPTD
iCO mean (L/min)	7.4	7.2	5.5	5.4	8.5	7.9	8.7	8.3	7.5	7.2
SD (L/min)	2.2	1.7	1.9	2.2	2.5	2.3	2.2	1.9	2.5	2.3
Bias (L/min)	0.29		0.19		0.57		0.37		0.35	
LoA	−1.88 to 2.46		−2.14 to 2.51		−3.15 to 4.29		−2.17 to 2.92		−2.30 to 3.01	
PE	29.2%		41.5%		43.8%		29.3%		35%	
Spearman's rho	0.871		0.852		0.700		0.816		0.835	
Concordance correlation coefficient	0.849		0.856		0.688		0.818		0.840	
Precision (Pearson ρ)	0.8817		0.872		0.710		0.843		0.852	
Accuracy (correction factor C_b)	0.963		0.981		0.969		0.970		0.986	
Angular bias	−4.96		−0.81		1.29		2.92		−6.34	
SD of angular bias	43.08		39.6		38.11		39.88		22.43	

PT pulmonary thermodilution, *TPTD* transpulmonary thermodilution, *iCO* intermittent cardiac output, *SD* standard deviation, *LoA* 95% limits of agreement (LoA), *PE* percentage error

the overall Spearman's coefficient of rank correlation (rho) between the PT-iCO and TPTD-iCO was 0.835 ($p < 0.0001$) with a concordance correlation coefficient of 0.840 (95% confidence interval [CI] 0.795–0.877), a precision (Pearson ρ) of 0.852, and an accuracy (bias correction factor C_b) of 0.986 (Table 2). For completeness of information, we also reported the scatter diagram with local regression smoothing trend line (LOESS) (Online Supplemental Material 1), measurement comparisons between PT-iCO and TPTD-iCO for every phase, and the totals.

3.3 Methods trending ability

According to Critchley et al. [15, 16] we also compared the trending ability of the two methods by means of 4-quadrant plots and polar plots, considering differences between iCO values measured at different times but during the same phase (Figs. 2, 3). After the exclusion of points in the ±0.5 L/min central zone, angular biases were found to be acceptable (see Table 2), which means that the two methods are fairly well calibrated to each other. The concordance rate between the two techniques in 4-quadrant plot analysis was 44, 60, 59, and 58% during basal, anhepatic, reperfusion, and end of surgery phases respectively, for an overall value of 65% for all pairs. The concordance rate of the polar plot turned out instead to be 37% during basal phase, 44% in anhepatic, 51% at reperfusion and 44% at the end of surgery, for an overall value of 83%.

3.4 Patient outcome

No intraoperative major complications were encountered with the use of both cardiac output monitoring devices. A femoral catheter was damaged at the end of the surgery and then removed.

4 Discussion

The main finding of this study is that, during liver transplantation, the TPTD-iCO measured by the EV1000 showed an overall percentage error of 35%, compared to the PAC PT-iCO. This value lies beneath the acceptable threshold of 45% recently proposed by Peyton and Chong [17], but above the statistical cut-off of 30% first described by Critchley and Critchley [18]. However, analysing the different phases, the percentage error was 29.2% in the basal phase, 41.5% in the anhepatic phase, 43.8% at the reperfusion and 29.3% at the end of surgery. Previous studies in liver transplantation, that compared the PiCCO TPTD iCO/CCO versus the PAC PT-iCO, showed somewhat similar results: a relatively small mean difference and limits of agreement with an acceptable accuracy

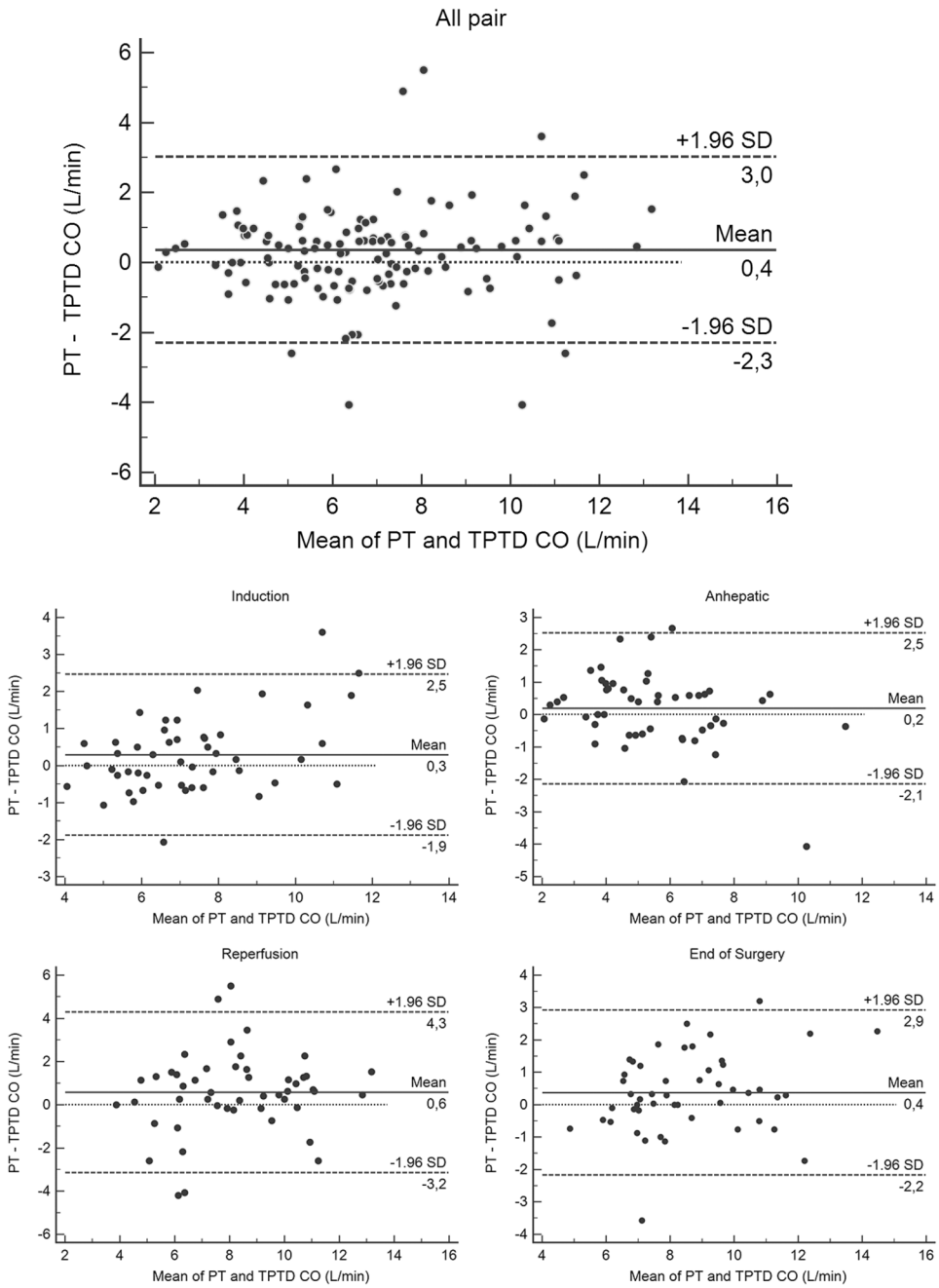

Fig. 1 Bland–Altman plots for measurements comparisons of PT-iCO and TPTD-iCO in every phase, and totals

and precision in the early phase of transplantation, but markedly decreased accuracy and precision after inferior vena cava clamp and graft reperfusion [19–22]. Recently, Vilchez Monge et al. [23] studied the widest sample of measurements available during liver transplantation, analysing the agreement between the TPTD-iCO and CCO provided by the $PiCCO_2$ system and the PT-iCO provided by PAC. They found that TPTD-iCO shows a percentage error of 45% during hepatic dissection phase, while anhepatic phase shows no agreement between TPTD-iCO and PT-iCO with a percentage error of 52%. When compared with our results, the new EV 1000 system appears to show a lower percentage error during all phases of the transplant.

To our knowledge there is only another study similar to ours, in which the TPTD-iCO measured with the new EV 1000 system is compared to the PT-iCO of the PAC. This study is that of Park et al. [24], in which the authors obtained a total of 375 paired datasets from 25 patients undergoing living donor liver transplantation. However, in that study the authors connected the PAC to a Vigilance monitor (Edwards Lifesciences) to obtain a CO value measured by

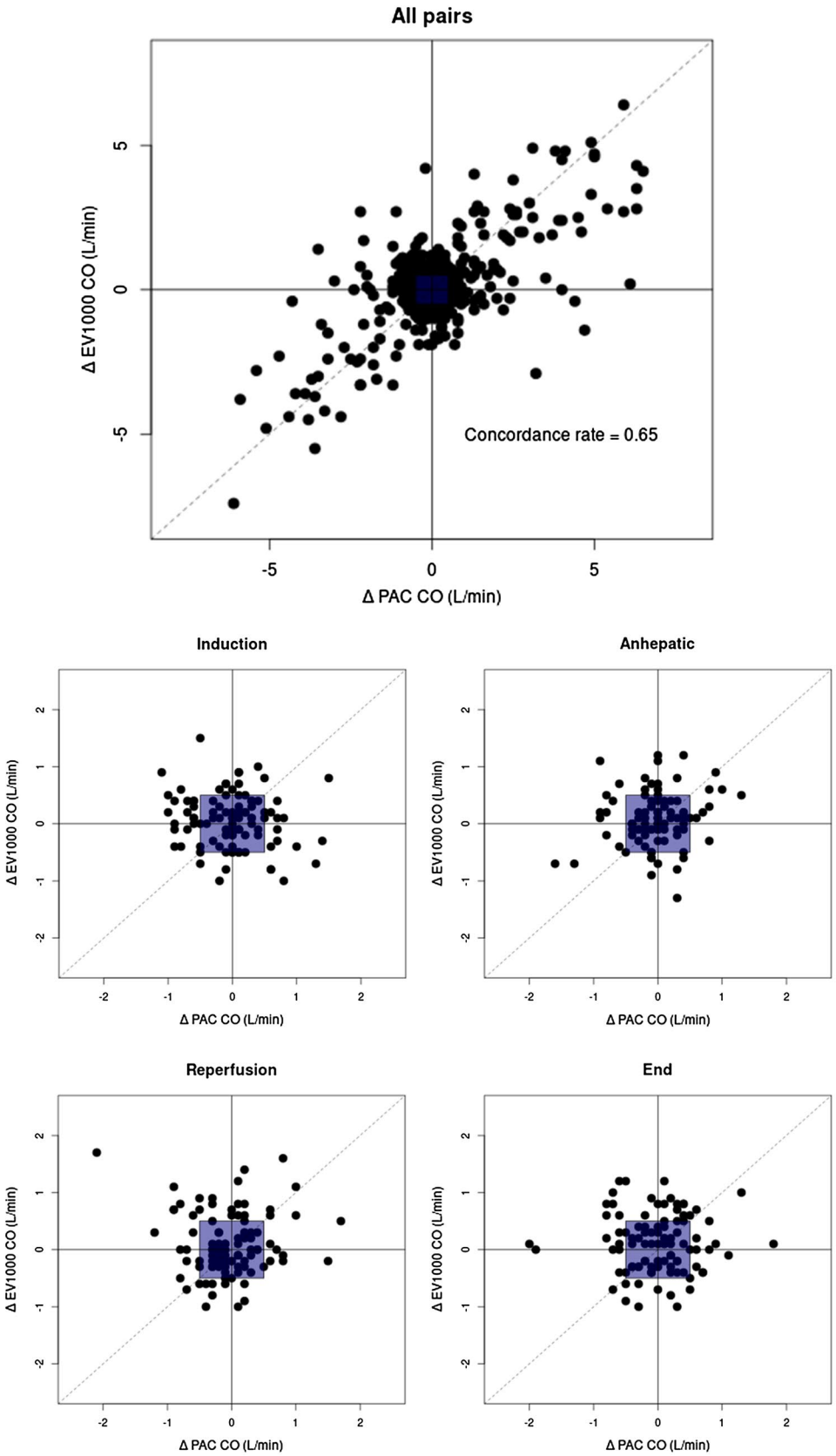

Fig. 2 Four quadrant scatter plots with linear regression line comparing changes in measurements of PT-iCO and TPTD-iCO in every phase, and totals. Data points within the ±0.5 L/min exclusion zone (blue box) are excluded from analysis

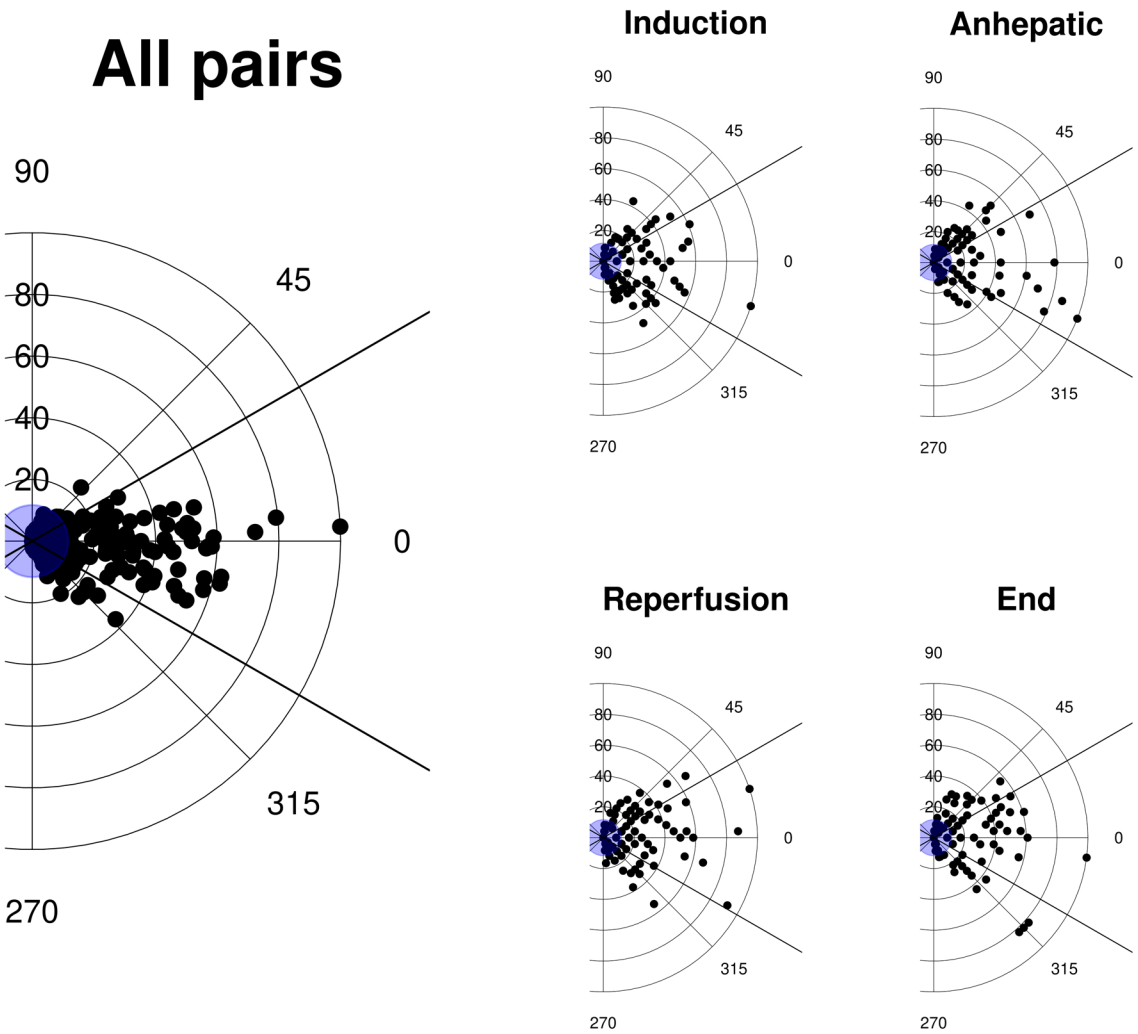

Fig. 3 Polar plot comparing changes in measurements of PT-iCO and TPTD-iCO in every phase, and totals. Data points within the ±0.5 L/min exclusion zone (blue circle) are excluded from analysis

STAT-mode. The STAT-mode provides CO measurements that are time-averaged over the preceding 1 min. In this way the authors showed an overall percentage error of 42.3%. Therefore, our study show a fairly good agreement between the EV1000 TPTD-iCO and the PAC PT-iCO during liver transplantation surgery.

The EV1000 monitoring platform (Edwards Lifesciences) has been validated in animal models, assessing global end-diastolic volume (GEDV) and extra-vascular lung volume (EVLW) and comparing these values with those provided by the PiCCO system. However, the authors did not compared the TPTD-iCO with PT-iCO [8].

The agreement between EV 1000 and PiCCO in measured TPTD-iCO has been studied by Kiefer et al. [25]. In their multi-center clinical study, the authors found an high agreement of these two devices, and they also found that trending capability was interchangeable. When compared with our results, in the stable phase of transplantation, PT-iCO provided by PAC compared with the TPTD-iCO obtained with the EV 1000 system, showed a fair accuracy and precision. However, trending ability between the two devices was questionable probably due to rapid hemodynamic changes of the transplant.

Some considerations need to be done. In their theoretical study, Critchley and Critchley [18] suggested that an acceptable agreement should be defined as a percentage error of 30% or less, when both the gold standard and the new method in evaluation have a precision of ±20%. The PT-iCO provided by PAC has been considered the gold standard, but in the studies of Mackenzie et al. [26] and Stetz et al. [27] the CO values measured by the PAC were obtained under conditions of hemodynamic stability and outside of the operating theatre. During liver transplantation, anhepatic and reperfusion phases are associated with the greatest cardiovascular hemodynamic instability, with large sudden variations of volemia and vascular resistance

[28]. In particular the reperfusion phase is mainly a feature of the piggy-bag technique, in which the de-clamping of the portal and sopra-hepatic vein anastomosis lead to graft reperfusion [11]. This may induce a characteristic pattern named post-reperfusion syndrome (PRS) characterized by very low vascular resistance, the mechanisms and pathophysiology of which are complex and not yet fully understood [29]. Another factor to consider is that the percentage of error of PAC, compared to the aortic flow probe (the real goal standard in measuring cardiac output), turned out to be $\geq 40\%$, bringing therefore to the assumption that the precision of PAC is beyond the proposed 20% value suggest by Critchley and Critchley [30]. Based on this finding Payet et al. suggest that a percentage of error of $\pm 45\%$ should be accepted in clinical practice, instead of the 30% value proposed before [17]. Last but not least, another consideration need to be done: PT-iCO measures the right heart cardiac output while TPTD-iCO measures the left heart cardiac output. These two systems are totally different in size, shape, architecture, and function. Although their balances must be maintained under equilibrium conditions, this require a little bit of time, especially when changes happen suddenly [31]. For example, after the caval clamping, the CO of the right ventricle decreases before the left one. Similarly, after reperfusion, the preload of the right heart cavities can increase by three times, and it may take a few minutes before a new equilibrium is reached between the two systems of the heart. Furthermore, it has been shown that clinical conditions characterized by rapid changes in central and peripheral vascular compartments are associated with long-lasting differences in central and peripheral temperature [32]. This also helps to explain the measurement differences between PAC and EV1000, since they are different systems in which the PAC thermistor resides in the central thorax compartment, while the EV1000 thermistor resides in the periphery. Finally, with regard to the second aim of this study, the 4-quadrant plots and the polar plots analysis showed a questionable trending ability between the measurements during each phase of surgery. In that way our result are in line with the study of Vilchez Monge et al. [23].

4.1 Limitations

Our study has some limitations: It is a single center observational study. We did not know PAC precision and we did not study the EV1000 performance after fluid challenge. iCO with PT and TPTD technique has its inherent pitfalls: loss of indicator before, during and after injection, variation of injected temperature, recirculation in case of shunt and tricuspid regurgitation, etc. We also need to acknowledge the fact that we did not recorded the thermal difference between central and peripheral compartment and that the EV1000 catheter was inserted 4 cm below the inguinal line, under ultrasound (Supplemental Digital Material 2), just a little bit lower than usual.

5 Conclusion

In conclusion the present study, in liver transplantation patients found that TPTD-iCO obtained with the EV1000 system showed a percentage error in the acceptable threshold of 45% when compared with the PAC catheter. On the others hands, our results showed a moderate-poor trending ability between the two techniques.

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Compliance with ethical standards

Conflict of interest All authors have no conflict of interest to declare.

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