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A NEW NON-INVASIVE CONTINUOUS CARDIAC OUTPUT TREND SOLELY UTILIZING ROUTINE CARDIOVASCULAR MONITORS

COMPARISON WITH THE CONTINUOUS THERMODILUTION METHOD EARLY AFTER CARDIAC SURGERY

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ABSTRACT. Objective. Three of the us developed a new non-invasive continuous cardiac output (CCO) measurement method utilizing routine clinical monitors based on the pulse-contour analysis combined with pulse wave transit time (PWTT). Using pulmonary artery catheter (CCOpa), we compared this estimated CCO (esCO) with the thermodilution CCO early after cardiac surgery, and tested whether the esCO method has potential of being an alternative measure of CCO. **Methods.** Thirty-six patients without continued arrhythmias were studied. esCO was computed using electrocardiogram (ECG) monitor, arterial pressure monitor and pulse-oximetry system. Both sets of data (esCO and CCOpa), by averaging the results of the preceding 10 min, were compared at 30-min intervals throughout the 15.8 ± 3.3 h (S.D.) of study. Bland–Altman plots and correlation analysis were used for statistical comparison. **Results.** A total of 981 paired sets of data (89.9%) among 1093 measurements were compared in the absence of displacement of either pulse-oximetry or ECG probes and/or inaccurate detection of R wave. The difference between esCO and CCOpa results was -0.06 ± 0.82 L/min (S.D.), and there was a linear correlation between them ($r = 0.80$, $p < 0.0001$). The difference between them was 0.00 ± 0.48 L/min at the first 1 h, which remained unchanged throughout 20 h after the start of measurement. **Conclusions.** The results demonstrate that esCO has a close correlation with the CCOpa, even though the two methods are not interchangeable. The results suggest that esCO method has potential of being an alternative non-invasive cardiac output trend, unless there are apparent arrhythmias.

KEY WORDS. Measurement technique, cardiac output, pulse contour analysis, thermodilution, cardiac surgery, postoperative period.

INTRODUCTION

Continuous cardiac output (CCO) measurement derived by thermodilution method is being widely used to optimize cardiovascular management of critically ill patients in a timely fashion. However, this method requires invasive procedures for placement of a specially designed pulmonary artery catheter. Recently, less invasive methods such as arterial pulse-contour analysis, bioimpedance analysis, transesophageal Doppler method, and partial CO_2 rebreathing method, have become available to measure CCO. However, even these less invasive methods generally require additional probes or sensors other than the routine cardiovascular monitoring equipment such as electrocardiogram (ECG). It would be clinically relevant to measure CCO solely with routine cardiovascular monitors without requiring any further sensors or procedures for it.

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Three of the us from Nihon Kohden Corporation have developed a new measurement method for determining estimated continuous cardiac output (esCO) based on pulse-contour analysis [1] combined with pulse wave transit time (PWTT) [2] as an alternative method to measure CCO with routine cardiovascular monitors, including ECG, arterial pressure monitor and pulse-oximetry without applying any additional probes or sensors to the patient. A more detailed description of the new method is provided in the appendix.

In this study, we compared the esCO with the thermodilution CCO using pulmonary artery catheter (CCOpa) in the early postoperative period after cardiac surgery and tested whether the esCO method has potential of being an alternative to CCO.

MATERIAL AND METHODS

The study was approved by our institutional review board, and each patient gave written informed consent before surgery. Patients with significant tricuspid valve insufficiency were excluded from the study, as a high degree of tricuspid regurgitation has potential of underestimation of thermodilution CO [3]. Forty consecutive patients (ASA physical status 2 and 3) scheduled for elective cardiac surgery, including off-pump coronary artery bypass grafting, were initially enrolled. Exclusion criteria of patients are described in more detail in the appendix. The greatest care was not taken to avoid any intervention that could have an effect on the hemodynamic state, such as alteration of ventilator setting, change of drug therapy, rapid volume loading, and verbal or physical contact with the patient, while measurements were being taken during the study.

A balloon tipped flow-directed thermodilution pulmonary artery catheter (Swan-Ganz CCOmbo CCO/SVO2, ref. 744HF75, Baxter Healthcare, Edwards Critical Care Division, Irvin, CA, USA) was placed in the operative room for CCOpa measurements. Correct position was confirmed by pressure tracing as well as chest radiography. This catheter was connected to a CCOpa monitor (Vigilance®, Revision 4.4, Baxter Healthcare). A period of 30–60 min was allowed to stabilize the patient's condition after admission postoperatively to the intensive care unit (ICU). The esCO system was also connected to an ECG monitor, arterial pressure monitor and pulse-oximetry system. Subsequently, both CCOpa and esCO measurements were started. As esCO consistently requires a reference cardiac output (CO) value utilizing another CO measurement system, a corresponding CCOpa value was applied as a reference when esCO was started. esCO data were continuously retrieved at every 1 min. Row data retrieved directly from the output terminal of CCOpa monitor were used for comparison. The first comparison was made at 30 min after the start of simultaneous measurements, and comparison was continuously performed at a 30-min interval before the patient was discharged from the ICU, or as long as the pulmonary artery catheter remained in place. Data of both CCO measurements were averaged for the preceding 10 min throughout the study period, as one can expect approximately a 5–15-min delay to register a patient's true CCOpa from acute hemodynamic changes [4–6].

Measurement of bolus thermodilution CO was also performed in the last 24 patients immediately before the end of measurements. Ten milliliters of chilled isotonic saline $<8\ ^{\circ}C$ were injected through the injectate port of the pulmonary artery catheter. Measurements were performed in triplicate at random points of the respiratory cycle. A variation of $\pm 15\%$ within triplicate measurements was defined to be acceptable.

Data are expressed as mean $\pm$ S.D. Bland–Altman plots were used to compare the bias (the mean of the differences) and precision (S.D. of bias) between the two methods. Regression analysis was also performed. Bias between esCO and CCOpa at a 30-min interval was analyzed using ANOVA for repeated measurements. Statistically significant difference was considered when $p < 0.05$.

RESULTS

Four of the 40 patients were excluded from the study. Three patients had irregular R–R intervals throughout their stay in the ICU: persistent atrial fibrillation, frequent ventricular premature contractions and failure of accurate R wave detection, respectively. Thus, they met the exclusion criteria of esCO measurement in this study, and the calculation process of esCO was discontinued automatically. The other patient was discharged from the ICU, 3 h after his admission to the ICU due to emergency admission of another patient. The study period for this patient was too short to be included in the study. Consequently, a total of 36 patients were finally enrolled in the study (Table 1). Although the study period was initially planned to maximally extend throughout the first 24-h postoperative period, it actually ranged between 12 and 23.5 h, with an average of 15.8 ± 3.3 h (S.D.).

The trachea was extubated in 32 patients during the study period by an average of 5.1 ± 5.3 h (S.D.) after admission to the ICU, and remained intubated in the remaining four patients during the study period. Throughout the study period, 15 patients received an infusion of vasopressors such as dobutamine and/or norepinephrine at least 5 h after admission to the ICU, six patients received an infusion of nicardipine to normalize hypertension, and one patient

Table 1. Patients demographics

No. of patients (male/female)	36(22/14)
Age (years)	66.7 ± 10.2 (43–79)
Body weight (kg)	58.3 ± 11.1 (39–91)
Body surface area (m^2)	1.58 ± 0.18 (1.26–2.01)
Operative procedures	
Aortic arch replacement	8
Valve surgery	4
Valve surgery + CABG	5
CABG	2
OPCAB	17
Duration of measurement (h)	15.8 ±3.3 (12 – 23.5)

Data are presented as mean ± S.D. (range) or number.
CABG: coronary artery bypass grafting; OPCAB: off-pump coronary artery bypass grafting.

received an infusion of lidocaine to overcome ventricular premature contractions. In addition to routine fluid administration, 23 patients had blood transfusion or volume loading with either colloids and/or crystalloids when clinical judgment of hypovolemia was made, and 13 patients had transient volume loading at least twice during the study period. Consequently, only 10 patients had a relatively stable hemodynamic state, without any additional therapeutic interventions throughout the study period.

A total of 1093 paired data were automatically obtained and reviewed by three of the us from Nihon Kohden Corporation, but 112 of the esCO data measurements were judged inadequate. As determined by prospective exclusion criteria, displacement of the pulse-oximetry probe occurred on 36 occasions in seven patients and displacement of ECG probes occurred on 33 occasions in five patients, respectively. The remaining 43 esCO data had a problem of wave recognition. Obvious temporary sinus arrhythmias, which could considerably affect the calculation process of esCO, were observed on 24 occasions in one patient. This inaccuracy was detected automatically, and excluded from the esCO data. Inaccurate R wave detection for calculation of PWTT occurred temporally on 19 occasions in one patient, whose S wave was wrongly identified as R wave. This inaccuracy was not detected automatically, but was found after careful review of each wave by all three of the us. Thus, a total of 981 paired data (89.9%) were finally used to compare esCO with CCOpa.

There was a bias of −0.06 ± 0.82 L/min (S.D.) between esCO and CCOpa associated with a linear correlation between the two measurements ($r = 0.80$, $p < 0.0001$, $n = 981$) (Figure 1). There were 53 data in 12 patients among 981 measurements (5.4%) that distributed beyond 95% confidence intervals (2S.D.) of differences between esCO and CCOpa.

The bias was 0.00 ± 0.48 L/min between esCO and CCOpa at the first 1 h, and remained unchanged throughout 20 h from the start of measurement (Figure 2).

The bias was −0.63 ± 1.01 L/min between esCO and bolus CO associated with a linear correlation between measurements ($r = 0.82$, $p < 0.001$, $n = 24$) (Figure 3). The bias was −0.64 ± 0.84 L/min between CCOpa and bolus CO associated with a linear correlation between measurements ($r = 0.91$, $p < 0.001$, $n = 24$).

The mean PWTT during the study period in each individual patient ranged from 172.2 to 376.0 ms, as shown in Table 2.

No correlation was found between PWTT and CCOpa-derived stroke volume (SV) ($r = -0.059$), as shown in Figure 4.

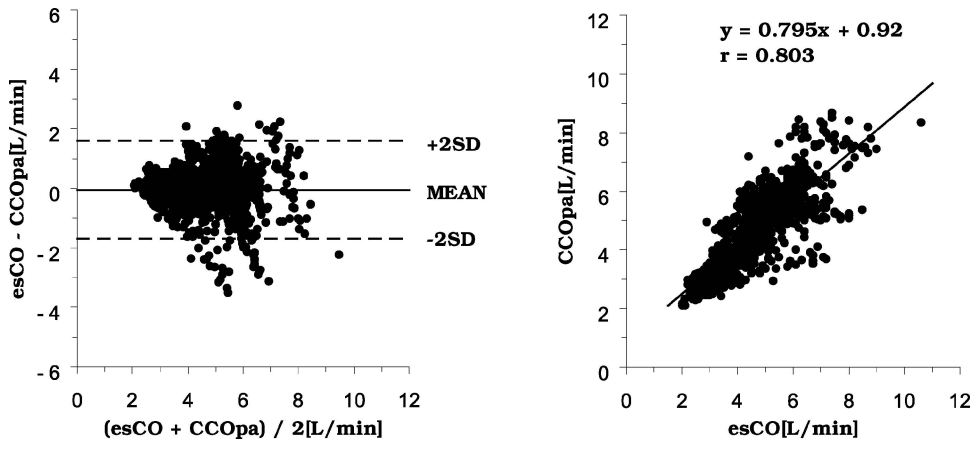

Fig. 1. A bias and precision between estimated cardiac output (esCO) and continuous cardiac output (CCO) using pulmonary artery catheter (CCOpa) (left) associated with a linear correlation between the two measurements (right).

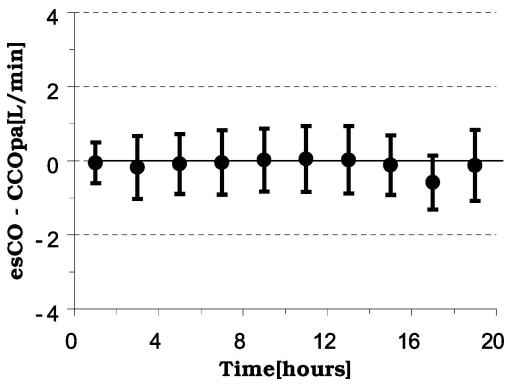

Fig. 2. Changes of bias between estimated cardiac output (esCO) and continuous cardiac output (CCO) using pulmonary artery catheter (CCOpa) during the study period.

DISCUSSION

The present study demonstrates that the bias between the two measurements was less than 0.1 L/min, indicating the absence of any significant systematic error between the two measurements. Della Rocca et al. [7] reported the difference of CCO using arterial pulse wave analysis (PiCCO system, Pulsion Medical System, Munich, Germany) and CCOpa during liver transplantation. The bias between the two methods was –0.03 L/min and the precision (S.D. of differences) was 0.87 L/min. Felbinger et al. [8] also reported the difference between CCO using arterial pulse-contour analysis calculated with a new algorithm and CCOpa following elective cardiac surgery. The bias between the two methods was –0.14 L/min/m^2 and the precision was 0.328 L/min/m^2. Thus, the bias and precision in the present study was comparable with these two reports. Based on their conclusions that arterial pulse-contour analysis agrees with CCOpa, esCO would also be clinically useful, even though the two CCO measurements in this study were not interchangeable, as judged by the limits within which the two methods are judged to be interchangeable to ±0.5 L/min [9].

We initially believed that the trend of relative CO values would be more clinically relevant than intermittent accurate CO values, as superiority of CCOpa to bolus CO has been reported in critically ill patients [10]. Thus, comparison of esCO with bolus CO was conducted only in two-third of the patients within this study. The bias and precision between esCO and bolus CO at the end of measurement in these patients were comparable with the bias and precision between CCOpa and bolus CO in this study. Whereas, reported bias and precision of the latter were 0.06 L/min and 0.76 L/min after cardiac surgery during periods of hemodynamically stable states [9]. When compared with this study, the precision of esCO was comparable with CCOpa's, but its bias seemed to be greater than that of CCOpa's. This is probably because calibration of the esCO system with CCOpa was performed only at the start of measurement, and the greatest care was not taken to avoid any intervention that could have had an effect on hemodynamic states during the study period. Considering these different measurement conditions, esCO and CCOpa would be equivalent when compared with bolus CO as a reference. However, further studies are required to evaluate esCO with intermittent measurements of bolus CO within a defined interval.

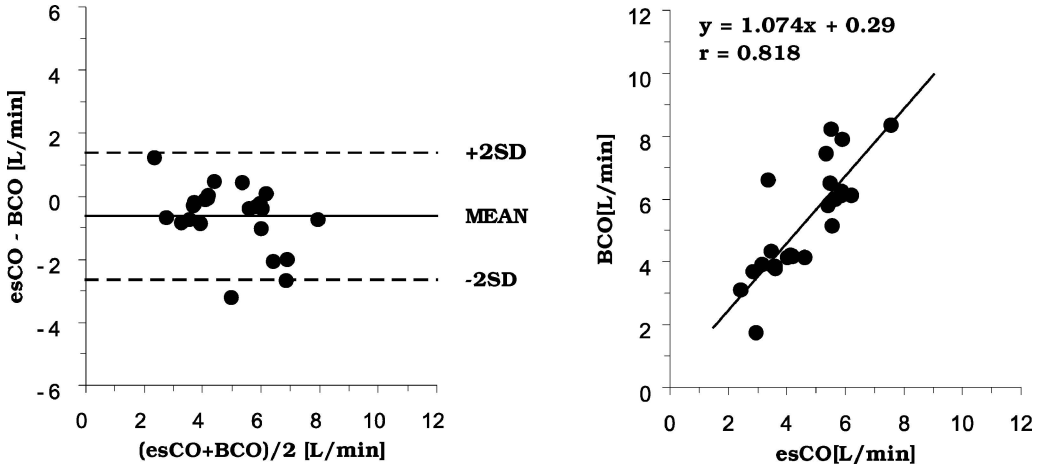

Fig. 3. A bias and precision between estimated cardiac output (esCO) and bolus cardiac output (BCO) (left) associated with a linear correlation between the two measurements (right).

Table 2. PWTT during study period in each patient

Patient	PWTT (ms)
1	216.6 ± 10.4 (199.8–237.6)
2	233.8 ± 7.1 (220.1–248.3)
3	287.6 ± 13.4 (266.7–331.2)
4	211.4 ± 5.5 (196.5–219.5)
5	202.6 ± 6.6 (193.8–217.9)
6	223.0 ± 7.1 (206.6–235.6)
7	178.7 ± 4.4 (172.2–186.0)
8	215.4 ± 14.2 (198.1–276.0)
9	229.7 ± 6.4 (217.8–246.7)
10	249.2 ± 25.6 (229.6–365.8)
11	245.8 ± 3.2 (239.8–251.6)
12	249.3 ± 5.5 (235.5–258.1)
13	227.7 ± 9.0 (217.1–239.9)
14	261.9 ± 21.6 (220.6–300.4)
15	233.4 ± 5.7 (222.6–245.9)
16	229.1 ± 19.1 (201.2–264.9)
17	227.8 ± 3.5 (221.0–233.9)
18	246.2 ± 6.3 (233.5–257.0)
19	308.1 ± 14.5 (285.5–338.4)
20	242.2 ± 12.2 (225.7–265.8)
21	222.2 ± 5.6 (211.7–234.7)
22	326.3 ± 50.5 (246.6–376.0)
23	234.5 ± 12.3 (204.0–257.6)
24	232.1 ± 10.8 (208.5–253.1)
25	238.1 ± 10.9 (224.5–258.0)
26	238.3 ± 11.2 (220.9–265.0)
27	223.5 ± 6.3 (213.8–245.7)
28	259.4 ± 9.9 (240.0–279.8)
29	217.8 ± 8.0 (206.6–240.4)
30	253.8 ± 10.2 (239.8–273.7)
31	280.0 ± 8.6 (253.8–296.4)
32	257.0 ± 13.5 (234.5–277.3)
33	296.6 ± 2.9 (290.4–301.8)
34	241.5 ± 6.0 (231.8–253.3)
35	252.2 ± 9.8 (230.8–272.1)
36	232.1 ± 4.8 (223.6–240.1)
Total	242.7 ± 31.4 (172.2–376.0)

Data are presented as mean ± S.D. (range).

As the esCO data obtained for this study was collected during routine postoperative ICU management, rather than in a controlled research-oriented management situation, inadvertent displacement of the pulse-oximetry probe and/or ECG probe as well as unstable hemodynamic states such as arrhythmias did not allow us to obtain the same sampling size from each patient during a certain timeframe. As a consequence, inadequate esCO data sampling was observed in approximately 10% of the data in this study, which would raise the criticism on the reliability of esCO measurement. However, approximately 60% of inadequate data was obtained due to inadvertent removal or displacement of either the pulse-oximetry probe or ECG probe during the routine postoperative management, rather than the research-oriented management, leading to automatic discontinuation of data collection. The remaining approximately 40% was also automatically excluded because of inadequate detection of R wave on ECG monitor. However, reviewing each ECG tracing by three of the us revealed completely inaccurate calculation of esCO on 19 occasions (1.7% of total collected data) in one patient, whose S wave was wrongly identified as R wave, indicating that esCO system has potential of being inaccurate unless R wave is clearly recognized. Although these inaccuracies would limit the effectiveness of esCO measurement, the amount of inadequate esCO data resulting from abnormal ECG was still less than what we had initially expected.

Approximately 5% paired data distributed out of 95% confidence limits (2S.D.) of differences between esCO and CCOpa measurements. Inaccuracy can potentially result from either method. Although data that met the exclusion criteria of esCO measurement have been automatically excluded from the study, other unknown undesirable conditions for esCO measurement may play a role, requiring further detailed studies. Inaccuracy of the CCOpa method also seems likely, shortly after cardiac surgery where alterations of CO such as titration of vasopressors, hemorrhage, cardiac tamponade, and rapid intravascular volume restoration [5, 9, 11] may occur rapidly. CO of CCOpa system is assumed to be constant by this method during the interval analyzed by the cross-correlation algorithm; however, when CO changes, this assumption is violated and the accuracy of CCOpa measurement is diminished until steady-state conditions are restored [12]. In fact, a considerable number of patients received an infusion of vasopressors and/or rapid administration of fluids or blood during the study period. Additionally, one can expect approximately 5–15-min delay to register a patient's true CO from acute hemodynamic changes, even though the instrument is operating in its fastest (STAT) mode [5, 6, 13]. Presumably, an average CCOpa value during the preceding 10 min, which was the method used in this study, would fail to consistently follow acute hemodynamic changes and thus would play a role in a large difference between the two measurements. According to our preliminary calculation, variability of either CCO value using an average of the preceding 50 min became smaller compared with values of the preceding 10 min in the present study. However, considering clinically relevant CO measurement, we used the average flow of

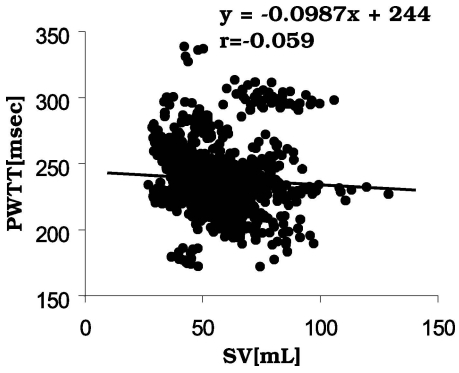

Fig. 4. The relationship between pulse wave transit time (PWTT) and stroke volume (SV) derived from thermodilution cardiac output measurement.

the preceding 10 min for both measurements in this study. Whereas, in our unpublished preliminary canine experimental study, we tested the relationship between esCO and CO derived from an electromagnetic flowmeter on the aorta during acute hemodynamic changes induced by administration of various cardiovascular drugs, hemorrhage and/or blood transfusion. The former, calculated by averaging consecutive eight heart beats, even correlated with the latter ($r = 0.83$, $n = 560$, $p < 0.001$). Further studies are required to determine whether esCO or CCOpa measurement has potential of being a more accurate CCO measurement during acute hemodynamic changes.

The pulse-contour analysis for CCO measurement must be "recalibrated" every 4 h [14] or when changes of systemic vascular resistance became greater than approximately 20% [15], even though its inaccuracy was not observed even with substantial changes in systemic vascular resistance during liver transplantation [7]. Although the vascular resistance may change considerably during the early post-cardiac surgery, the difference between esCO and CCOpa remained unchanged throughout 20 h, even when only one calibration was performed with CCOpa at the start of measurement. PWTT, which is the major determinant of esCO measurement, was reported to be unchanged despite changes in systemic vascular resistance [2]. Presumably, esCO would be relatively accurate even after changes in systemic vascular resistance.

Limitations of applying the esCO system include arrhythmias such as atrial fibrillation and ventricular premature contractions, use of either a cardiac pacemaker or intra-aortic balloon pumping and/or suboptimal signal for pulse-oximetry, because each results in automatic discontinuation of esCO calculation. However, its major limitation is the calibration requirement that necessitates utilizing another CO measurement system at the start of measurement. Nevertheless, measurement of esCO may be outweighed by the advantages of automated and continuous monitoring, depending solely on routine hemodynamic monitors. In conclusion, an analysis of the clinical validation of esCO measurement in comparison with CCOpa measurement early after cardiac surgery shows a linear correlation between both methods, even though they are not interchangeable. The result suggests that esCO measurement has potential of being an alternative non-invasive CCO trend, unless significant arrhythmias are present.

APPENDIX: THEORETICAL BACKGROUND

A pulse-contour analysis can measure SV and CO using arterial pressure and heart rate [1].

SV and CO are derived as follows:

$$\mathrm{SV} = K \times \mathrm{PP} \tag{1}$$

$$\mathrm{CO} = K \times \mathrm{PP} \times \mathrm{HR} \tag{2}$$

where PP is the pulse pressure, HR the heart rate, and K the experimental constant in each subject.

In esCO method, PWTT is a major determinant for calculation of CO. PWTT is the sum of pre-ejection period (PEP) and pulse wave arrival time from the ascending aorta to the peripheral pulse-oximetry (SpO_2) probe site, and its changes have been reported to predict changes in blood pressure [2]. PWTT is calculated from the interval between R wave of ECG and peripheral SpO_2 pulse wave arrival when ECG and SpO_2 are simultaneously recorded, as shown in Figure 5. The point of SpO_2 pulse wave arrival is defined where the differentiated signal reaches to 30% of the peak differentiated value, as reported previously [2].

We assumed that PP could be described by PWTT as follows.

$$\mathrm{PP} = \alpha \times \mathrm{PWTT} + \beta \tag{3}$$

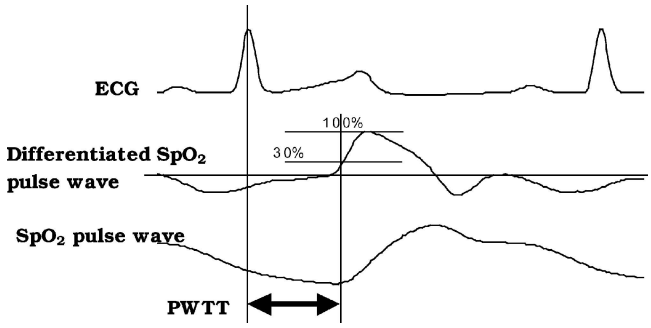

Fig. 5. The representative drawing of electrocardiogram (ECG), pulse-oximetry (SpO_2) pulse wave, differentiated SpO_2 pulse wave and pulse wave transit time (PWTT).

α, β are experimental constants. According to Equation (3), α is determined from changed values of both PP and PWTT, and is found relatively constant, namely -0.30 for humans, which has been determined from unpublished preliminary data in 14 patients. β is then calculated according to Equation (3), and is found variable in each individual subject. The mean β value determined at the start of measurement was 131.9 ± 16.5 (S.D.) in this study.

CO is derived as follows:

$$CO = K \times (\alpha \times PWTT + \beta) \times HR \quad (4)$$

K is derived from PWTT, HR and CO at the start of measurement in each patient according to Equation (4). Accordingly, a CO value derived by another CO measurement system is consistently required at the start of esCO measurement. In this study, CCOpa was used for this purpose. The mean K value was 0.96 ± 0.31 (S.D.) in this study. According to Equations (1) and (4), SV is derived as follows:

$$SV = K \times (\alpha \times PWTT + \beta) \quad (5)$$

Data Processing and Exclusion Criteria

PWTT is calculated by averaging 64 consecutive data of heart beats. Average PWTT and heart rate are based on data retrieved within every 1-min interval. Data with a large variability in PWTT (>20 ms) or pulse amplitude deviating from median values (>30%) during calculation are also excluded. Additionally, calculation process of PWTT is automatically violated when more than 25% of these 64 heart beats data are excluded in the following conditions:

1. Either ECG or pulse-oximetry pulse wave signal is not obtained.
2. Either R wave on ECG or the start point of the ascending portion of pulse-oximetry wave is not clearly identified.

esCO is then calculated using the averaged PWTT data of the preceding 10 min. Data of inadequate conditions which remain unchanged throughout the preceding 10 min are also excluded automatically.

We thank Dr P. Hollister (Misawa, Japan) for his valuable comments.

GLOSSARY

CCO	continuous cardiac output
CCOpa	continuous thermodilution cardiac output using pulmonary artery catheter
ECG	electrocardiogram
esCO	estimated continuous cardiac output
ICU	intensive care unit
PEP	pre-ejection period
PWTT	pulse wave transit time
SpO_2	peripheral pulse-oximetry

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