Fighting Disease with Electronics

NIHON KOHDEN

Performance Report

Redefine your quality of care with esCCO

A Novel Technology to Non-invasively Measure Continuous Cardiac Output from ECG and SpO_2

VOLUMETRIC INFORMATION FOR ALL CARE LEVELS

Nihon Kohden is redefining Quality of Care with new, non-invasive technologies like PWTT and esCCO by introducing volumetric information to all care levels. Estimated Continuous Cardiac Output (esCCO) is a new technology to determine the cardiac output using Pulse Wave Transit Time (PWTT). PWTT is obtained by the familiar vital sign parameters of ECG and pulse oximetry. With esCCO, cardiac output can be measured continuously with a very simple and totally non-invasive process.

The research and development goal for esCCO was to provide volumetric information especially for mid and low care levels, to improve patient care and enhance patient safety.

PULSE WAVE AND PWTT

Since the invention of pulse oximetry by Nihon Kohden researcher Takuo Aoyagi in 1974[1)], the pulse wave has become the most commonly used vital signal in clinical practice. The pulse wave can provide time related information such as intravascular pressure transmission as well as information about the volume change of arterial blood.

Pulse Wave Transit Time (PWTT) is defined as the time from the ECG R-wave peak to the pulse wave rise point. The pulse wave rise point is defined as the point where the differentiated pulse wave reaches 30% of its peak amplitude[2)]. PWTT consists of three intervals: pre-ejection period (PEP), pulse wave transit time through elastic artery (T_1), and pulse wave transit time through peripheral arteries (T_2). PEP is defined as the time from the ECG R-wave to the rise point of the aortic root pressure wave. T_1 is defined as the time from the rise point of the aortic pressure wave to the rise point of the radial artery pressure wave. And T_2 is defined as the time from the rise point of the radial artery pressure wave to the rise point of the pulse oximetry wave measured by an SpO_2 probe on the fingertip.

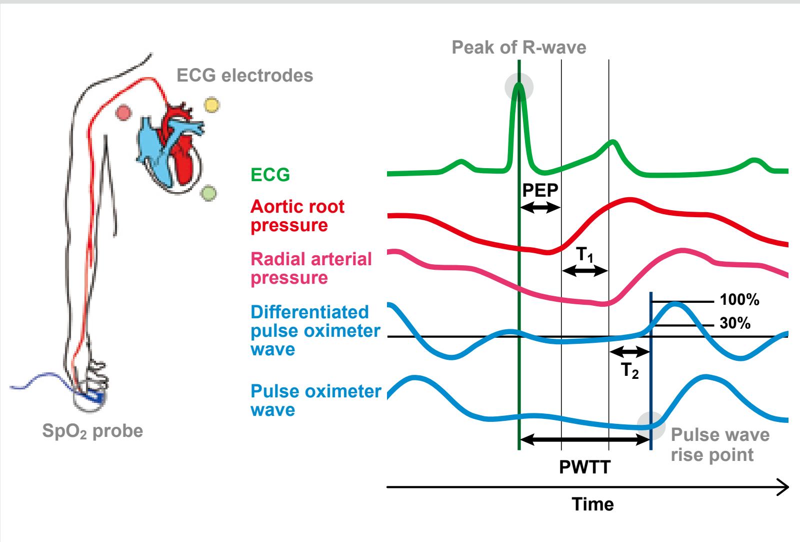

Figure 1.
Components of PWTT

PEP (pre-ejection period)
T_1 (PWTT through elastic artery)
T_2 (PWTT through peripheral arteries)
PWTT(Pulse Wave Transit Time)

PRINCIPLE OF esCCO

Cardiac output can be derived from pulse pressure information by the following equation:

$$CO = SV \times HR = (K \times PP) \times HR$$

where CO = cardiac output, SV = stroke volume, HR = heart rate, K = a constant, and PP = pulse pressure which was established in various continuous cardiac output systems using pulse contour analysis.

This was the starting point for the novel technology of esCCO. The correlation between SV and PWTT was observed to be better than the correlation between SV and PP (**Figure 2**) and the following formula provides cardiac output values from PWTT information.

$$CO = SV \times HR = K \times (\alpha \times PWTT + \beta) \times HR = esCCO$$

where α and β are experimental constants.

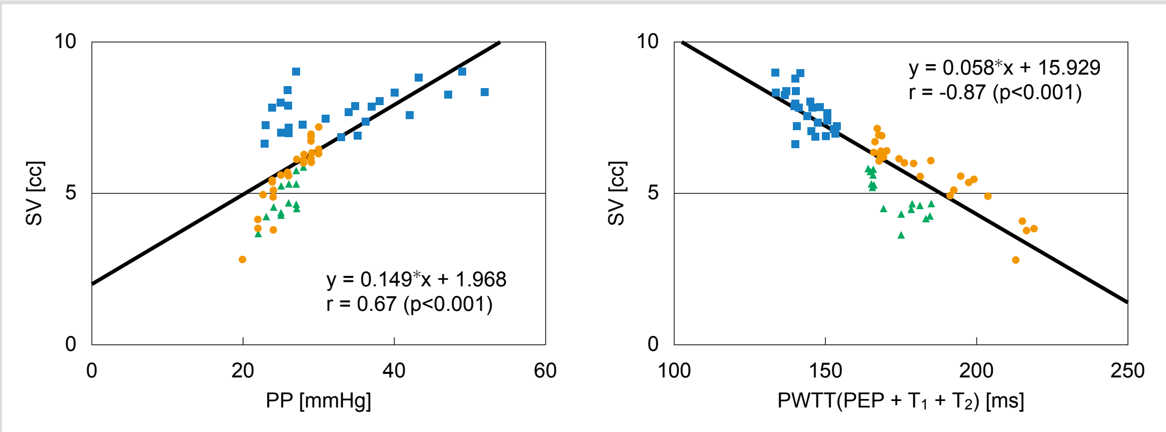

Figure 2. Comparison between pulse pressure (PP), pulse wave transit time (PWTT) and stroke volume (SV) of an anesthetized mongrel dog in conditions of varied circulation dynamics

Yellow circles, green triangles, and blue squares show the data at the administration of pentobarbital, the removal of blood, and the administration of phenylephrine, respectively[2].

EVIDENCE BASED PERFORMANCE

In 2004, Ishihara et al. reported that esCCO derived from PWTT information is highly correlated with intermittent cardiac output determined by thermodilution (ICO)[3]. In 2009, a multicenter study at seven facilities verified the effectiveness of esCCO as a practical application. The following section describes the performance and effectiveness of esCCO by summarizing a *Euroanaesthesia 2010* presentation of the multicenter study.

VERIFICATION OF A NON-INVASIVE CONTINUOUS CARDIAC OUTPUT MEASUREMENT METHOD BASED ON THE PULSE-CONTOUR ANALYSIS COMBINED WITH PULSE WAVE TRANSIT TIME

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Presented at : Euroanaesthesia 2010

BACKGROUND

To measure cardiac output (CO) less invasively, various devices have been developed. The esCCO (estimated (ECG-SpO_2) continuous CO) measurement system (Nihon Kohden, Tokyo, Japan) is designed to measure CO non-invasively. It estimates CO with an electrocardiogram (ECG) and a pulse oximetry waveform. 36 and 15 cases of clinical use in its development process suggest it has a good measurement accuracy equivalent to CO measured by pulmonary artery catheter (PAC)[4)5)]. The purpose of this study is to evaluate whether esCCO had a sufficient accuracy for practical use in a large number of patients in multicenter settings.

METHODS

With IRB approval, 109 elective surgery patients who needed PAC insertion were enrolled. Patients who received circulation support with artificial pacemaker or intra-aortic balloon pump were excluded. After the esCCO system and PAC installation, CO was determined by cold bolus thermodilution (ICO) and esCCO measurements were started. Concurrently, ICO and continuous thermodilution cardiac output (CCO) measurement was started. ICO and CCO measurements were performed periodically, once an hour in the operation room (OR) and once a day in the intensive care unit (ICU). Data recording was continued until PAC removal. For statistical analysis, Bland-Altman analysis and regression analysis were performed.

RESULTS

Correlation between esCCO and ICO

A total of 587 measurement pairs were obtained from 213 patients (74 in OR and 139 in ICU). The patient demographics are shown in **Table 1**. Forty-six pairs were excluded as invalid data. Correlation between esCCO and ICO was r=0.82 ($p<0.01$) and bias ± precision (1 standard deviation) was 0.08 ± 1.07 (L/min) in the Bland-Altman plot (**Figure 3**).

There were no significant differences between mean value of esCCO and ICO (significance level: 0.05). 95% confidence intervals for bias between mean values of esCCO and ICO were 0.04 to 0.22. They are within the range of ± 0.3 (L/min), which is considered acceptable for clinical use[6)].

Table 1. Patient demographics

Site	n	duration (h)	age (y)	sex (M / F)	height (cm)	weight (kg)	BSA (m^2)	CO range (L/min)
Total	213	26.2 ± 25.2	65.1 ± 12.7	142 / 71	160.0 ± 10.3	59.2 ± 12.5	1.61 ± 0.20	15.5 - 1.3
ICU	139	36.0 ± 26.2	65.7 ± 11.4	94 / 45	159.5 ± 9.9	59.4 ± 13.1	1.61 ± 0.20	15.5 - 1.5
OR	74	7.6 ± 2.9	64.0 ± 14.8	48 / 26	160.9 ± 11.0	58.7 ± 11.4	1.61 ± 0.19	13.1 - 1.3

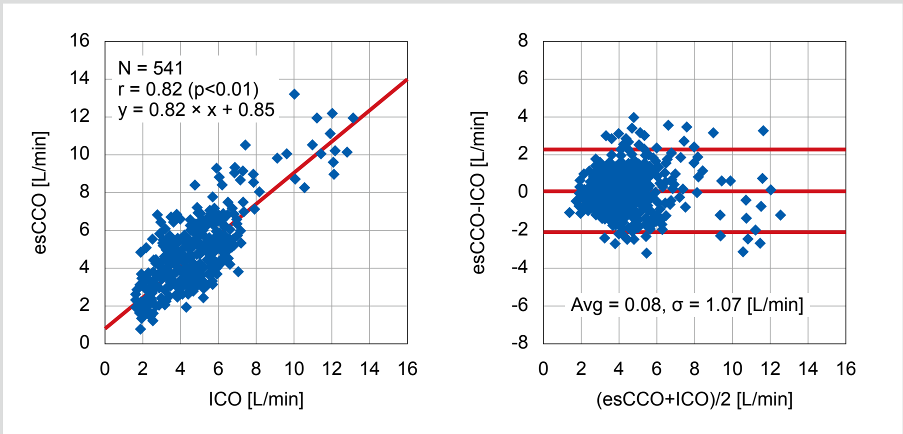

Figure 3.
Comparison between esCCO and ICO

Correlation between esCCO and CCO

esCCO showed a good correlation between CCO as well. A total of 549 measurement pairs were obtained and 45 pairs were excluded as invalid data. Correlation between esCCO and CCO was r=0.84 (p<0.01) and bias ± precision (1 standard deviation) was -0.07 ± 1.23 (L/min) in Bland-Altman plot (**Figure 4**). The variance of gap increased as time passed. Some factor examinations revealed that the precision increased after cardiopulmonary bypass (**Table 2**). Invalid data were related with heart manipulation and ECG abnormality (**Figure 5**).

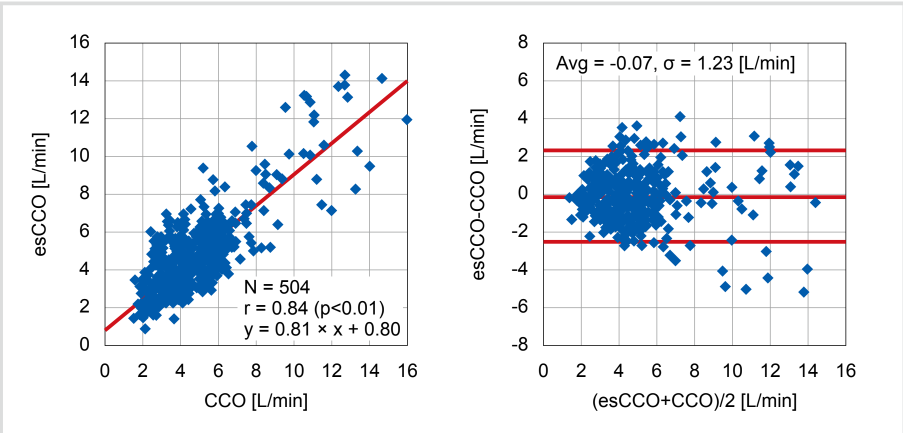

Figure 4.
Comparison between esCCO and CCO

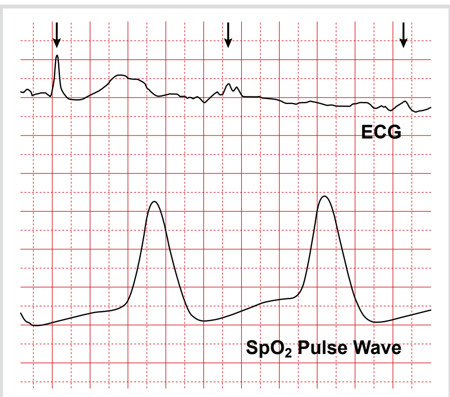

Figure 5.
Changes in ECG wave pattern due to heart manipulation

Table 2. Accuracy change over cardiopulmonary bypass (CPB)

	n	bias (L/min)	precision
Before CPB	22	-0.415	0.998
After CPB	42	0.237	1.92

ENHANCING QUALITY OF HEMODYNAMIC MANAGEMENT WITH esCCO

Monitoring cardiac output (CO) is very important in circulation management in the operating room (OR) and intensive care unit (ICU) especially for patients with unstable hemodynamics. In this section, we will describe one of the cases from the multicenter study to show how esCCO could be effective in hemodynamic management.

POSTOPERATIVE CHANGE IN CARDIAC OUTPUT OF A LIVER TRANSPLANT PATIENT IN THE ICU

Cirrhosis is accompanied by various cardiovascular abnormalities which increase cardiac output and decrease arterial blood pressure and vascular resistance[7]. Therefore, perioperative monitoring of these parameters is extremely important for liver transplant patients.

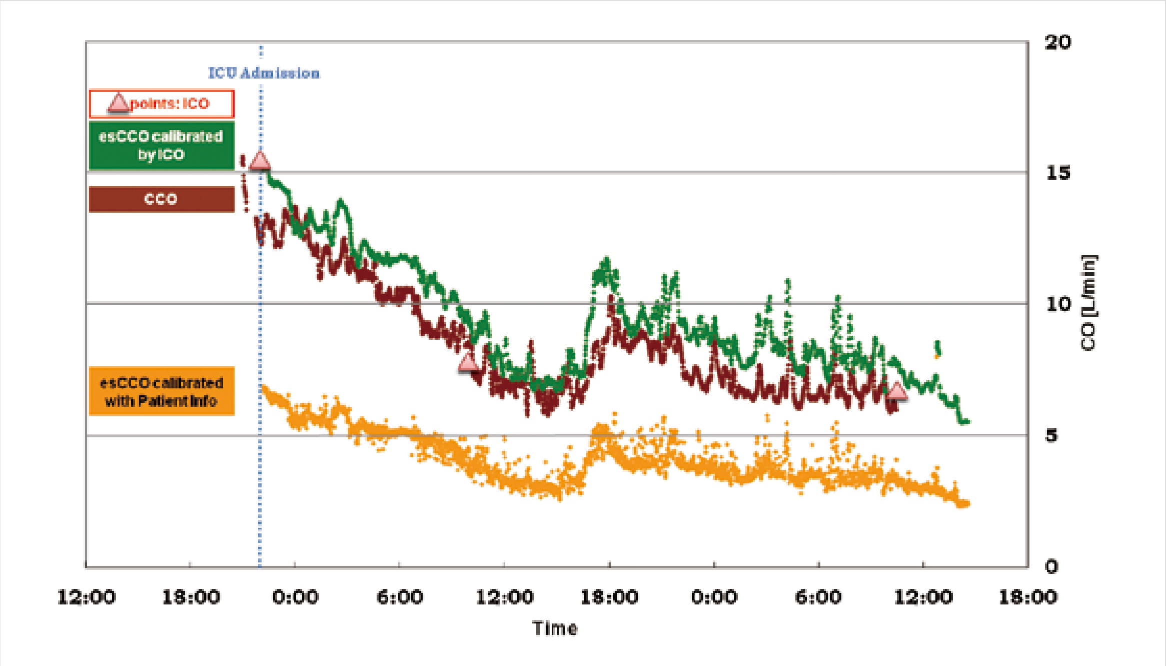

Figure 6. Comparison of esCCO, ICO, CCO in ICU post liver transplantation

Figure 6 shows esCCO trend observed in a patient (36 year old male, BSA 1.87m^2) in the ICU after liver transplantation. The intermittent cardiac output by cold bolus thermodilution (ICO) is shown by red triangles. The esCCO, which was once calibrated by ICO on ICU admission, was in excellent agreement with ICO and CCO (brown line) by pulmonary artery catheter (PAC). Despite the underestimation of CO due to decreased vascular resistance, esCCO calibrated with patient information (gold line) shows an equivalent trend to CCO. These results indicate that esCCO has a promising performance for tracking changes in CO after PAC removal.

RELIABLE MEASUREMENT WITH NON-INVASIVE CALIBRATION

For safe and less stressful patient care, the challenge was to avoid any kind of invasive or non-invasive calibration. By only entering patient information such as age, gender, height and weight, and an initial NIBP measurement, esCCO determines a reference value for calibration and is ready for start of measurement. Additionally, a cardiac output value obtained by other CO devices such as a PAC can be used for calibration. As shown in **Figure 6**, both calibration modes reliably track changes in cardiac output and provide advanced monitoring of a patient's hemodynamic status.

POTENTIAL APPLICATIONS OF esCCO

• General monitoring of patients in OR, ICU and ER
• Hemodynamic monitoring after PAC removal
• Hemodynamic optimization of patients who are ineligible for PAC
• Support in the decision making process for goal-directed fluid management and more

This easy and simple hemodynamic monitoring with esCCO could become a new standard for patient monitoring in every stage of patient care.

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