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**Validation of a continuous, arterial pressure-based cardiac output
measurement: a multicenter, prospective clinical trial**

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Abstract

Introduction: This study compared measurements of cardiac output by an arterial pressure-based analysis method (APCO) with measurement by intermittent thermodilution via pulmonary artery catheter in a clinical setting.

Methods: This multicenter, prospective clinical investigation enrolled patients with a clinical indication for cardiac output monitoring and who required pulmonary artery and radial artery catheters for that hemodynamic monitoring at two hospitals in the United States, one in France, and one in Belgium. In 84 patients (69 surgical), cardiac output was measured by analysis of the arterial pulse using APCO, and via pulmonary artery catheter by intermittent (ICO) thermodilution and, to establish a reference comparison, continuous cardiac output (CCO). Data were collected continuously by APCO and CCO technologies, and at least every four hours by ICO. No clinical interventions were made as part of the study.

Results: For APCO compared with ICO, bias was 0.20 L/min, precision was ± 1.28 L/min, limits of agreement were -2.36 l/m to 2.75 l/m. For CCO compared with ICO, bias was 0.66 L/min, precision was ± 1.05 L/min, limits of agreement were -1.43 l/m to 2.76 l/m. The ability of APCO and CCO to assess changes in cardiac output (Δ CO) was compared with that of ICO. In 96% of comparisons, APCO tracked Δ CO in the same direction as ICO. Magnitude of change was comparable 59% of the time. For CCO, 95% of comparisons were in the same direction, with 58% of those changes being of similar magnitude.

Conclusions: In critically ill patients in the intensive care unit, continuous measurement of cardiac output using either APCO or CCO is comparable to ICO. Further study in more homogenous populations may refine specific situations where APCO reliability is strongest.

Introduction

Clinicians monitor hemodynamic variables to diagnose conditions and follow treatment in critically ill patients. In the intensive care unit (ICU) and operating room (OR), such monitoring often includes cardiac output and, although potentially measured by newer techniques, usually requires placement of a pulmonary artery catheter. Intermittent (bolus) thermodilution cardiac output (ICO) measurement is a standard to which other methods of cardiac output measurement are compared. [1] Pulmonary artery catheterization has come under increasing criticism regarding its risks and costs, and questions have arisen about its benefits. [2, 3] Consequently, technologies equally effective yet less invasive, safer, and simpler to use have been sought for cardiac output monitoring. [4, 5] One of the more promising approaches in the monitoring of cardiac output is the estimation of flow from analysis of the arterial pressure waveform.

Approaches to measuring cardiac output via peripheral artery catheter typically use algorithms by which the pulse wave is analyzed and then related to a numerical value for cardiac output. These devices often require frequent calibration to initiate monitoring and to accurately assess cardiac output during changing vascular tone. [6, 7] A new arterial pressure-based cardiac output device (APCO) uses access to the radial or femoral artery via a standard arterial catheter. This system (Vigileo/FloTrac; Edwards Lifesciences LLC, Irvine CA) allows determination of stroke volume based on arterial waveform characteristics and individual patient demographics, without calibration. [8-11]

This study compares measurement of cardiac output by analysis of the arterial pulse using APCO with measurement by ICO. The study was designed to determine if cardiac output measurements obtained using APCO are comparable to those obtained using a clinically accepted method such as room temperature ICO [12, 13]. Continuous cardiac output (CCO) measured with a pulmonary artery catheter also was compared with ICO in order to show the

performance of a widely used continuous cardiac output measure against ICO. The less-invasive APCO technology may provide an additional option to improve hemodynamic management in critically ill patients, including those who currently are not monitored via pulmonary artery catheter but for whom continuous measurement of cardiac output and other flow-related parameters may allow timely identification of changes in hemodynamic status and rapid adjustment in therapy.

Materials and Methods

Adult patients requiring pulmonary and radial or femoral artery catheters as part of standard clinical care were enrolled from August 1 through December 15, 2004, at two U.S. and two European sites (Baystate Medical Center, Springfield, MA; Medical City Dallas Hospital, Dallas, TX; Centre Hospitalier Universitaire, Bordeaux Group Hospitalier Sud, Pessac, France; and Universitaire Ziekenhuizen Leuven, Leuven, Belgium), with each site enrolling at least 20 patients.

Pulmonary artery catheters (models 746HF8, 744HF75, 777HF8, or 774HF75; Edwards Lifesciences, Irvine, CA) were placed according to standard clinical practice for continuous and intermittent measurement of cardiac output using Vigilance™ monitors (Edwards Lifesciences). These catheters are equivalent in their ability to measure intermittent and continuous cardiac output. Catheter models differ in that some contain an additional volume infusion port, and some have the ability to measure right ventricular end-diastolic volume.

Radial and femoral arterial lines from a variety of manufacturers were connected to FloTrac™ sensors (Edwards Lifesciences), and cardiac output was determined using the algorithm used in the commercially available Vigileo™ APCO system (Edwards Lifesciences). [8] Hemodynamic data were monitored and recorded continuously and simultaneously with CCO and APCO, and intermittently using ICO. All hemodynamic

data were collected on laptop computers and downloaded to a remote system for analysis.

For each patient, data collected from the APCO device were compared with simultaneously collected data from the pulmonary artery catheter over a 24-hour period. During the first 12 hours of data collection, reference ICO measurements were collected every three hours. During the second 12 hours, these measurements were made every four hours. All measurements were made in the ICU. The intervals for data collection were established to mimic the standard of care for cardiac output measurements of the participating institutions. ICO values were obtained from the average of a minimum four room-temperature saline boluses injected at various times during the respiratory cycle[14]: 1) inspiration; 2) peak inspiration; 3) expiration; 4) end expiration. Additional ICO measurements depended on physician judgment and institutional practice. The physicians responsible for the care of these patients usually were the investigators. At least four complete sets of measurements were made for each patient. Cardiac output measurements derived from the APCO method were not used to guide therapy.

Baseline demographics and significant co-morbidities were recorded in a database for subsequent analysis, and patient identifiers were removed.

Cardiac output data were collected from all patients. Data consisted of cardiac output determined by APCO, CCO, and ICO during reference measurements every three or four hours throughout the monitoring period. Bias and precision analysis were used to compare cardiac output measurements from the pulmonary artery catheter with those calculated from the APCO technology. Bland-Altman plots were generated. [15] The difference between APCO and ICO values (and between CCO and ICO values) was determined for each set of cardiac output measurements. Mean and standard deviation

of the difference between cardiac output measurements were calculated to estimate bias and precision.

The ability to accurately measure change in cardiac output is important in clinical practice. [16] Although a clinically relevant change in cardiac output is unknown, for the purposes of our analysis we defined a significant change in cardiac output as 30%. In analysis of the direction and magnitude of change in cardiac output, ΔCO was calculated as the difference in cardiac output at two time points divided by the mean cardiac output at those two time points. ΔCO was expressed as a percentage by multiplying this quantity by 100% ($\Delta\text{CO}\% = [\text{CO}_i - \text{CO}_{i-1}]/[(\text{CO}_i + \text{CO}_{i-1})/2] \times 100\%$). Increases and decreases of the same magnitude had equivalent percentage changes that were opposite in sign.

The study protocol was approved by the institutional review boards and/or ethics committees of participating sites. All patients or their legal guardians provided prior written informed consent for participation in this study.

Results

Each of the study's four centers enrolled 20–23 patients, for a total of 86. One patient died after only one data set was collected, and another had no data logged due to technical difficulties. Of the remaining 84 patients, 69 had catheters placed during surgical procedures in the operating room before admission to the ICU. The other 15 were non-surgical critical care patients. All data was obtained in the ICU. All patients had pulmonary artery catheters placed, and all but one patient also had a radial artery catheter. One patient had a femoral artery catheter but no radial artery catheter, and another patient had radial and femoral artery catheters.

Approximately two-thirds of patients were male. Patients' ages ranged from 24–84 years, with a mean age of 68 years (Table 1). Patients had various co-morbid

diseases, and physicians placed pulmonary artery catheters for a variety of reasons (Table 2).

Bias of APCO compared with ICO was 0.20 L/min. Bias of CCO compared with ICO was 0.66 L/min.

For APCO relative to ICO, precision was found to be ± 1.28 L/min. Precision for CCO relative to ICO was ± 1.05 L/min. The limits of agreement for APCO vs. ICO were -2.36 to $+2.75$ L/min and for CCO vs. ICO were -1.43 to $+2.76$ L/min. Figure 1 shows the distribution of the difference between cardiac output measured by APCO and ICO plotted against the mean cardiac output determined by the two methods. [17] Lines show limits of agreement (dashed) and mean difference (solid). The figure also shows CCO vs. ICO plotted in a similar fashion. The coefficient of variation of ICO was 18%.

Changes in cardiac output are shown plotted in Figure 2. When Δ CO was measured by APCO, 59% of the time its magnitude and direction of change were within $\pm 15\%$ of the ICO measurement (Figure 2, e.g., Δ CO between -15% and $+15\%$ when measured by APCO, and Δ CO between -15% and $+15\%$ when measured by ICO). In 96% of Δ CO determinations, APCO's magnitude and direction of change were within $\pm 30\%$ of the measurement of ICO (Figure 2, e.g., Δ CO from -15% to $+15\%$ as measured by APCO but -45% to -15% or $+15\%$ to $+45\%$ as measured by ICO). And in 4% of determinations of Δ CO, the APCO measurement direction and magnitude of change differed more than $\pm 30\%$ from the measurements by ICO (Figure 2). For CCO compared with ICO, those percentages were 58%, 95%, and 5% respectively.

Discussion

Our data demonstrate that APCO co-varies with ICO in a series of critically ill patients over their initial 24 hours of ICU monitoring. The study population included patients with cardiac disease, multi-system organ failure, acute heart failure, and severe sepsis, as well as patients needing postoperative monitoring for cardiac surgery. Extensive data were gathered for 24 hours, comparable to studies of other methods for measuring cardiac output. [19, 20] Considering the limitation of the differences in measurement techniques that compare a continuous measure that gives a running average of cardiac output over 20 seconds (APCO) versus ICO which traditionally is obtained with a 4 second injection, APCO performance was similar to the well accepted thermodilution CCO methodology that averages CO over several minutes. Rapid dynamic changes in cardiac output that are seen in the clinical intensive care setting will contribute to the measurement differences we observed in our patients. Averaging cardiac output over longer time periods with thermodilution CCO may not well represent actual dynamic variation in SV and cardiac output when measured against techniques that evaluate CO during shorter time intervals.

This study is one of the largest clinical comparison studies of cardiac output monitoring. [10, 16, 21] We observed similar cardiac output measurements when comparing CCO with ICO, consistent with previous studies, [19, 20, 22, 23] when compared with ICO, APCO measurements appeared to be less biased overall than CCO measurements.

The standard deviation of the difference between measurement by APCO (or CCO) and ICO gives an estimate of the precision of the APCO (or CCO) measurement compared with the ICO measurement. [15] When comparing two imperfect methods of measurement that each have an error distribution, the resulting error distribution (in this

case) of the differences is wider than either of the two methods' error distributions, because occasionally overestimation by one method will be compared with underestimation by the other. For measurement of cardiac output, the most widely accepted standard is ICO. ICO typically has an error (standard deviation) of 10–20%. [13, 18, 21] ICO error was 18% in our patients. In our study, the overall “grand mean” cardiac output over all patients by all three methods of measurement was 5.9 L/min. The observed standard deviation for the difference between APCO and ICO measurement, ± 1.28 L/min, was $1.28/5.9 = 22\%$ of the grand mean cardiac output. The observed standard deviation for the difference between CCO and ICO, ± 1.05 L/min, was $1.05/5.9 = 18\%$ of the grand mean. The standard deviations for either method of continuous measurement of C.O. observed in this study are consistent and similar to ICO error on serial measures as we obtained it under real ICU conditions.

Limits of agreement have been used in discussions about comparisons of measurement methods. If 15% is the typical precision of ICO [21], then the limits of precision (95% confidence limits) are $\pm 30\%$, an error that has been considered clinically acceptable. [18] Two equivalent methods of measurement, each having $\pm 30\%$ limits of precision, would have limits of agreement for their difference of $\pm 42\%$. Thus, the APCO vs. ICO agreement of $\pm 43\%$ ($\pm 2 * SD/\text{mean cardiac output} = \pm 2 * 1.28/5.9$), and the CCO vs. ICO agreement of $\pm 36\%$ ($\pm 2 * SD/\text{mean cardiac output} = \pm 2 * 1.05/5.9$) found in this study were expected. Other investigators have suggested that two equivalent methods of measurement should have limits of agreement for differences of 28%. [18] However, that conservative estimate assumed precision of 10% for the methods of measurement, greater precision than generally is accepted for thermodilution, [13, 21] and significantly better than the 18% observed in this study.

Clinical changes in cardiac output (ΔCO) related to pathophysiology or treatments determine therapy at the bedside. Between method pairs [(APCO and ICO) or (CCO and ICO)], measurements of ΔCO by APCO compared with ICO were in either the same magnitude/same direction, or same direction/lesser or greater magnitude within an overall $\pm 30\%$ difference in magnitude in 96% of the paired measurements. More specifically, measurements were in the same direction and of the same magnitude as ICO ($\pm 15\%$) in 59% of comparisons. They were dissimilar to ICO in 4% of comparisons. This compares favorably with CCO measurements of ΔCO , which were in the same direction and magnitude as ICO in 58% of comparisons, same direction $\pm 30\%$ magnitude of change in 95%, and disparate to ICO in 5%. This comparison of magnitude and direction of change avoids the problem of exaggeration of inaccuracies at high values when comparing absolute changes measured by two systems and at low values when comparing relative (percentage) changes.

There are significant limitations to our study. The variability in the reference measure of ICO is higher than generally accepted. When comparing the continuous measures of cardiac output to the reference standard, this variability could allow the APCO technology to appear similar in reliability to CCO when in fact it is not. Further data must be generated in the controlled setting of the operating room in paralyzed patients to clarify this issue. Assuring accurate timing of cardiac output determination to the respiratory cycle will improve the reliability of ICO.

In assessing a diverse group of patients with various levels of vascular tone related to pathophysiology, vasopressors, volume status or other therapies, it remains unclear to what degree this may impact the determination of cardiac output from a peripheral artery. Including patients with various degrees of vascular tone impacted by their clinical condition, i.e., sepsis, multiorgan failure, and vasopressors, may limit

reliability of a technique that depends on arterial waveform analysis. Independent study of more homogenous groups such as severe sepsis with or without vasopressors will be required to answer these important questions.

There are many examples of patient subgroups that were included in our population that require independent validation. Patient specific issues related to vascular compliance and tone are the most obvious, but specific physiology, medications, and volume status may also impact cardiac output measurement from analysis of the arterial pulse. Simply its performance in the major shock categories warrants further investigation. The dynamic heterogeneity of our patients may limit evaluation of cardiac output utilizing the arterial pulse via a peripheral artery when compared to thermodilution. Studies in homogenous populations under similar conditions may shed light on this issue. Other issues that would limit the utility of arterial pressure and waveform assessment related to the arterial pulse are limitations of the device. A high fidelity reliable arterial waveform is essential to cardiac output determined in this manner. Significant aortic valvular disease or the presence of an intra aortic balloon pump would also be expected to influence cardiac output using arterial waveform analysis.

Conclusions

In our patients, APCO showed acceptable bias, precision, and measurement of cardiac output compared with ICO, the current standard. Thermodilution CCO, utilizing a pulmonary artery catheter, showed similar bias and precision as continuous APCO when compared to ICO. APCO appears to be a promising minimally invasive method of continuous cardiac output measurement that requires further investigation.

Key Messages:

APCO is a less invasive technique requiring simply an arterial catheter and does not require calibration or central venous access.

APCO compares favourably with CCO methodology using a PAC when bolus intermittent thermodilution is used as a reference in the ICU.

List of Abbreviations

APCO (arterial pressure-based cardiac output)

CCO (continuous cardiac output)

CO (cardiac output)

Δ CO (change in cardiac output)

ICO (Intermittent thermodilution cardiac output)

ICU (intensive care unit)

OR (operating room)

Competing Interests

Edwards Lifesciences, Irvine, California, provided a research grant for execution of the protocol described in the Materials and Methods section of this report. William T, McGee, M.D. and Jeffrey L. Horswell, M.D. have received consulting fees from Edwards Lifesciences. Dr. McGee is also on a speakers' panel for Edwards Lifesciences.

All data was collected at the four clinical sites by the investigators. Edwards Lifesciences received the electronic data for their critique of the technical aspects of the data collection and analysis.

Authors' Contributions

WTM, JLH, GJ, and GVdB were responsible for study design, data interpretation, and drafting the manuscript. WTM, JLH, JC, TVS and LK were responsible for data acquisition and analysis.

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Figure Legends

Figure 1. Mean difference in cardiac output measured by APCO and ICO or CCO and ICO as a function of mean cardiac output. In each panel, the difference in cardiac output as determined by two methods is plotted against the mean cardiac output ($[\text{APCO} + \text{ICO}]/2$ or $[\text{CCO} + \text{ICO}]/2$). The central solid line shows mean difference. Dashed lines show limits of agreement (95% confidence interval). 84 patients, 561 data points.

Figure 2. ΔCO measured by ICO and either APCO or CCO. ΔCO is the difference in two measurements (by one method) of cardiac output expressed as a percentage of the mean of those measurements. Points that fall within squares along the central diagonal (green squares) reflect equivalent changes for the test cardiac output measurement method (i.e., APCO or CCO) and ICO. Points that fall within the yellow squares reflect changes of similar direction but different magnitudes. Points that fall within white sections in the upper left and lower right reflect non-correlated changes between the test measurement method and ICO.

Table 1 Patient Characteristics

	Male (n=55)		Female (n=29)	
	Mean	Range ^a	Mean	Range ^a
Age (years)	67	24–84	69	45–83
Height (cm)	174	160–185	160	148–172
Weight (kg)	88.2	60.0–150.7	69.3	41.2–112.7
Body surface area (m ²)	2.07	1.66–2.54	1.71	1.33–2.11
Heart rate (beats per min)	86	57–116	87	57–117
Cardiac output (L/min) ^b	6.2	3.1–9.2	4.6	1.7–7.5
Cardiac index (L/min/m ²)	3.01	1.74–4.29	2.7	1.38–3.96
Stroke volume (ml)	72.2	37.7–106.8	54.4	16.1–92.8
Mean arterial pressure (mm Hg)	73.0	49.5–96.5	72.0	45.8–98.3

^aRanges for age, height, weight, and body surface area are min–max, and ranges for heart rate, cardiac output, cardiac index, stroke volume, and mean arterial pressure are $\pm 2SD$; ^bMean cardiac output as measured by APCO.

Table 2

Most Frequent Patient Co-morbidities			Most Frequent Reasons for Pulmonary Artery Catheter Insertion		
	n	%		n	%
Systemic hypertension	48	(57)	Cardiac Surgery	23	(27)
Coronary artery disease	29	(34)	Diagnosed cardiac disease	23	(27)
Valvular heart disease	28	(33)	Volume status	21	(25)
Diabetes	27	(32)	Perioperative monitoring	17	(20)
Hyperlipidemia	23	(27)	Multi-system organ failure	8	(10)
Angina	22	(26)	Acute heart failure	6	(7)
Arrhythmia	20	(24)	Severe sepsis	4	(5)
Congestive heart failure	18	(21)			

Multiple comorbidities coexist in many patients. In several patients, more than one reason was listed for pulmonary artery catheter insertion.

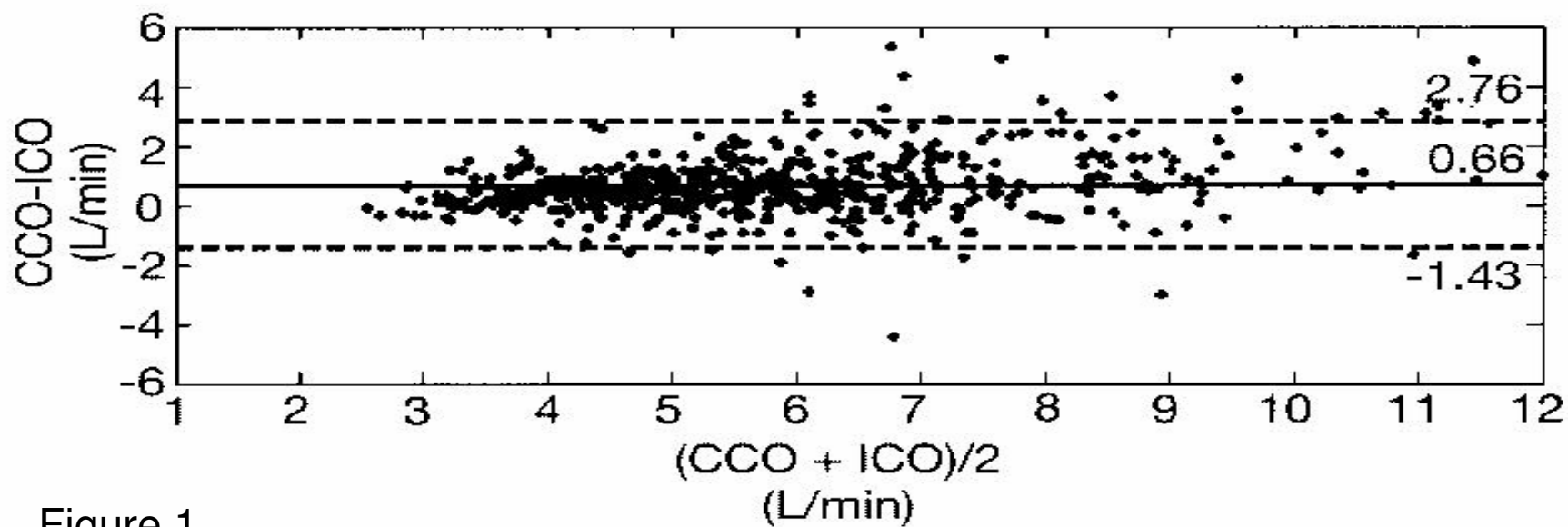
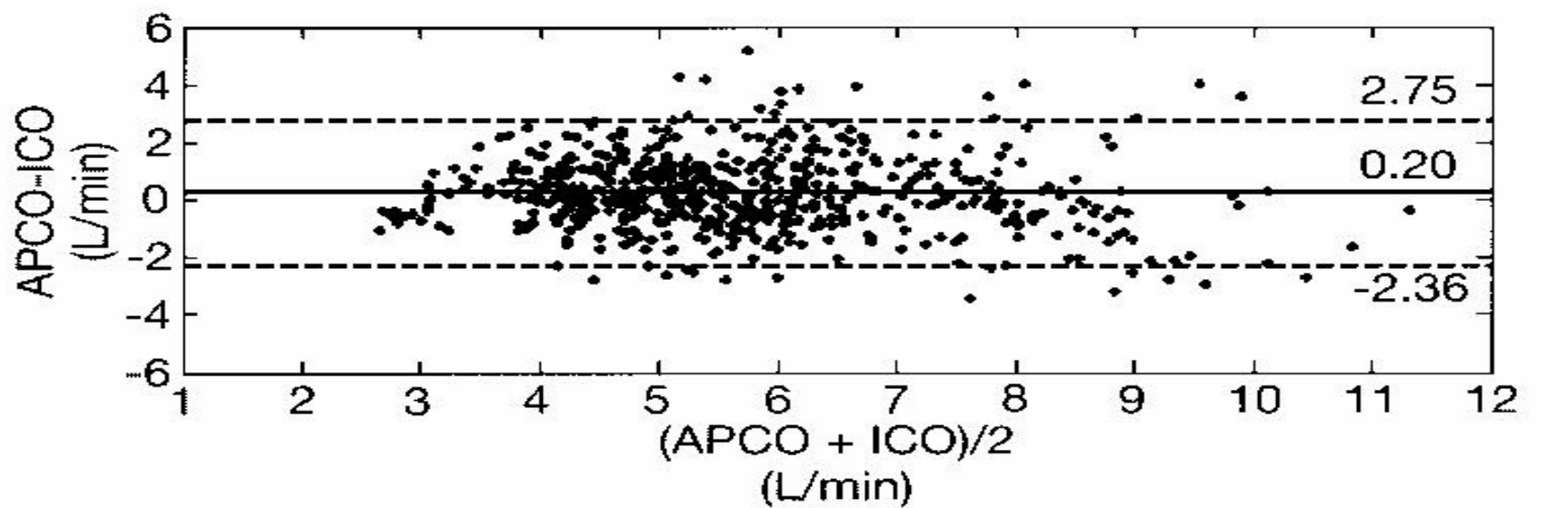


Figure 1

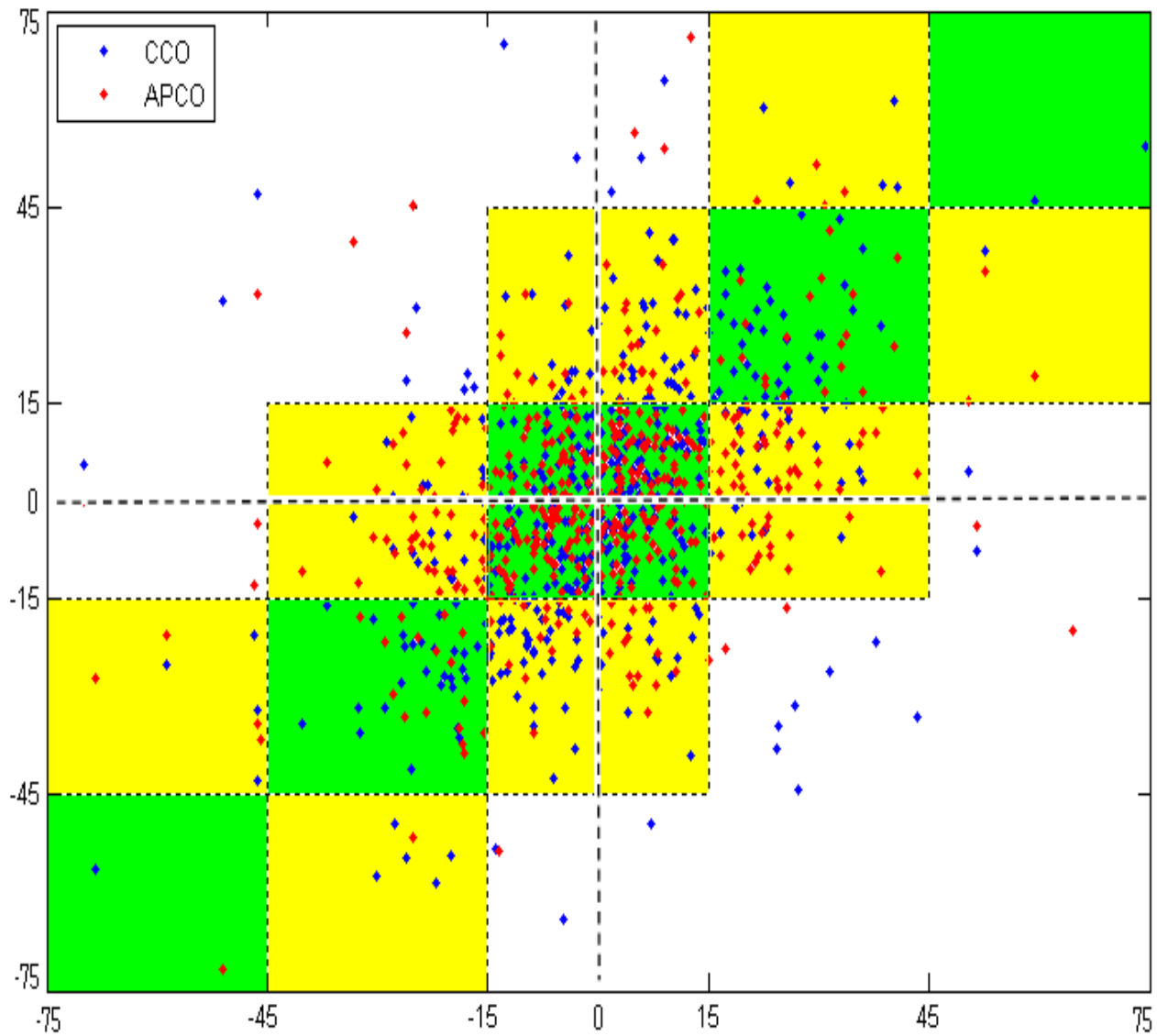


Figure 2: CCO - ◆
APCO - ◆