Equipment

Evaluation of a new semi-continuous cardiac output system in the intensive care unit

Philippe Seguin MD,
Olivier Colcanap MD,
Anne Le Rouzo MD,
Michèle Tanguy MD,
Yves-Marie Guillou MD,
Yannick Mallédant MD

Purpose: A new semi-continuous thermodilution cardiac output (CCO) system has been developed recently (Opti-Q™ and Q-vue™ Abbott critical care system). The aim of this study was to compare the accuracy and reproducibility of this new device with conventional ice-bolus thermodilution cardiac output (BCO).

Methods: Fifteen critically ill patients who needed pulmonary artery catheterization were prospectively investigated. Eighty seven paired data using BCO and CCO methods were compared. Reproducibility was assessed from 90 BCO and 87 CCO determinations by calculation of the mean standard error (SEM) and according to Bland and Altman methodology.

Results: The BCO and CCO ranged from 2.46 to 11.20 L·min^{-1} and from 1.75 to 10.05 L·min^{-1} respectively. Bias (mean difference between BCO and CCO) was null (0.002 L·min^{-1}, $P = 0.98$), precision (SD of the bias) was 0.74 L·min^{-1} and the limits of agreement (mean difference ± 1.96 SD) ranged from -1.45 to 1.45 L·min^{-1}. The threshold to consider two cardiac outputs as different (3 × SEM) was equivalent for BCO and CCO (0.54 and 0.465 L·min^{-1} respectively). According to the Bland and Altman method, reproducibility of CCO was greater than that of BCO: bias of repeated measurements of BCO and CCO were 0.15 L·min^{-1} ($P < 0.05$) and 0.047 L·min^{-1} (NS), respectively.

Conclusion: Compared with BCO, this new device was accurate but cannot be considered as interchangeable regarding the limits of agreement. Reproducibility of CCO was superior to BCO.

Objectifs : Récemment, un nouveau système de mesure semi-continue du débit cardiaque (CCO) a été commercialisé (Opti-Q™ and Q-vue Abbott critical care system). Le but de cette étude était d'évaluer les performances de ce nouveau système en comparaison à la thermodilution classique par injection de soluté froid (BCO).

Méthodes : Quinze patients de réanimation, pour lesquels l'indication d'un cathétérisme droit était posée, ont été prospectivement évalués. Quatre vingt sept couples de mesures étaient comparés. La reproductibilité était estimée par le calcul de l'erreur standard moyenne (SEM) et selon la méthode de Bland et Altman sur 90 mesures pour le BCO et 87 pour le CCO.

Résultats : Les BCO et CCO s'étendaient respectivement de 2,46 à 11,20 L·min^{-1} et 1,75 à 10,05 L·min^{-1}. Le biais (différence moyenne entre BCO et CCO) était nul (0,002 L·min^{-1}, $P = 0,98$), la précision (écart type du biais) était de 0,74 L·min^{-1} et les limites d'agrément (biais ± 1,96 écart type) s'étendaient de -1,45 à 1,45 L·min^{-1}. Le seuil pour considérer deux débits cardiaques comme différents (3 x SEM) pour BCO et CCO était équivalent (0,54 et 0,465 L·min^{-1} respectivement). Néanmoins selon la méthode de Bland et Altman, la reproductibilité du CCO était supérieure à celle du BCO: le biais de mesures répétées pour BCO et CCO était respectivement de 0,15 L·min^{-1} ($P < 0,05$) et 0,047 L·min^{-1} (NS).

Conclusions : Comparé à la thermodilution classique ce nouveau système de mesure en continu du débit cardiaque est suffisant en pratique clinique mais ne peut être réellement considérer comme interchangeable. La reproductibilité du CCO est supérieure au BCO.

From the Service d'Anesthesiologie-Réanimation Chirurgicale 1, CHR-U de Pontchaillou, 2, rue Henri Le Guilloux, 35033 Rennes Cedex, France.

Address correspondence to: Docteur Seguin Philippe, Phone: 33-2-99-28-4246; Fax: 33-2-99-28-4181; E-mail: yMalledant.rennes@invivo.edu

Accepted for publication March 13, 1998.

IN critically ill patients, cardiac output (CO) measurements, heart rate, blood pressure and oxygenation parameters are the main haemodynamic variables that provide diagnostic and prognostic information and allow therapeutic changes.[1–4] Since 1992, semi-continuous cardiac output (CCO) determination at the bedside with a modified pulmonary catheter has been available (Intellicath™ and vigilance™ system, Baxter Healthcare Corporation). Several studies have been conducted during anaesthesia and in intensive care units (ICU) to assess the agreement of this method versus conventional ice-bolus thermodilution (BCO) technique. In most studies, low levels of agreement were found, suggesting that the two methods were not interchangeable.[5–8] Reproducibility is another critical parameter to be taken into account and we have previously shown that CCO has less variability than BCO and that this could be explained by a lack of agreement between the two techniques.[8]

Based on the same principle, but with slight technical modifications, a new semi-continuous cardiac output pulmonary catheter has been developed (OptiQ™ and Q-vue™ system, Abbott critical care system). The aim of the present study was to evaluate the accuracy of this new device compared with conventional ice-bolus thermodilution cardiac output (BCO) and to compare the reproducibility of BCO and CCO methods.

Materials and methods

Patients

The study protocol was approved by the local institutional review board (Comité Consultatif de Protection des Personnes dans la Recherche Biomédicale. Date of acceptance: July 9 1996). Informed consent was obtained from the patients or, when patients were unable to give consent, from the nearest relative. All patients were undergoing mechanical ventilation. The haemodynamic status of the patients required a pulmonary artery catheter, according to the judgement of the physician in charge. Patients were excluded from the study if they were < 18 yr of age, had atrial fibrillation or a significant (>1 $m \cdot sec^{-1}$) tricuspid insufficiency determined by echocardiography (Sonos 1000. Helwett Packard).

Methods

The flow-directed thermodilution fibreoptic continuous cardiac output pulmonary catheter (OptiQ™, model 8F ST 52509, Abbott critical care system) was connected to a monitor (Qvue™, Abbott critical care system). The catheter has a 15 cm thermal filament coated with polyurethane which releases at regular intervals a defined level of heat into the bloodstream. The slight blood temperature change (output signal) was detected by a sensitive thermistor and correlated with the input signal to produce a thermodilution washout curve. Values were updated every 20 sec and the average of the last five minutes displayed. The upper temperature of the thermal filament was limited to 44C. After insertion into the heart, the filament was placed in the right ventricle for optimal CCO determination, this location being checked by the presence of a right ventricular pressure wave obtained with the distal thermal coil positioning port lumen (DTTP™). The monitor measured cardiac output by the traditional BCO method using the same catheter. During BCO determination, the CCO mode was inactivated and restarted later if required.

Protocol

After insertion, the overall position was checked by radiography (tip of the catheter near the right pulmonary hilus) and pressure measurements. The proximal port of the OptiQ™ Abbott critical care system was located in the right atrium for optimal BCO determinations. Technical trouble shooting and complications during insertion were noted. Measurements of cardiac output were carried out over six hours. Planned cardiac output determinations, using the continuous and bolus thechnique were performed every hour. The CCO value was measured and then a rapid series of three boluses of 10 ml ice-cold (< 5C) dextrose 5% solution was rapidly injected, asynchronously with the respiratory cycle. Thermodilution curves were plotted to detect artefacts (irregularities in the shape of the wave and no return to the baseline). The monitor was then reconnected to measure CCO and the CCO value after five minutes was recorded. The average of the three BCO values was then compared with the average of the CCO value obtained just before and five minutes after the bolus sequence. During the study, there was no change in mechanical ventilation parameters or in any therapeutic interventions. For each patient, six paired CO measurements were performed.

Statistical analysis

Paired data were plotted and the line of equality on which all points would lie if the two methods gave exactly same results. Agreement between CCO and BCO measurements was assessed by the method of Bland and Altman.[9,10] Bias is the mean difference (MD) between the two methods of measurement and

represents the systematic error. Bias was compared with ideal null bias (unpaired t test, $P < 0.05$ was considered as significant). Precision (the SD of the bias) is representative of the random error or variability between the two techniques. The MD ± 1.96 SD was the limits of agreement. If the limits of agreement are smaller than the threshold of clinical relevance, the two methods may be considered to be in agreement and, therefore, interchangeable. The threshold of clinical relevance selected was ± 1 L.min^{-1}.

The reproducibility of the BCO and CCO methods was first analyzed according to Stetz *et al.*:[11] the standard error of the mean (SEM) was the basis for predicting reproducibility. The SEM was derived by dividing the standard deviation of repeated measurements by the square root of the number of measurements (two for both BCO and CCO). The SEM was characteristic of the variability for each method or instrument. It may also be used to determine, for each method, the threshold required to differentiate two values of CO. A variation of three SEM is needed to be confident that two values of cardiac output are different. Reproducibility of both CCO and BCO was also analysed according to Bland and Altman.[9,10] Cardiac output measurements were determined before and after the series of bolus injections for CCO. Similarly, the first and third measurements of BCO were used as paired data. This method provided another aspect of reproducibility in addition to calculation of SEM. If bias is different from the ideal null bias, it can be conclude to a lack of reproducibility.

Data were analysed with Stat View 4.0 (1992 Abacus Concept, Berkeley, CA).

Results

Eighty seven data pairs from 15 patients admitted to the surgical intensive care unit were obtained. Mean age was 70 ± 10 yr (SD), mean SAPS II (Simplified Acute Physiology Score II) on admission was 52 ± 13.[12] Diagnoses included septic shock (n = 10), cardiogenic shock (n = 3) hypovolaemic shock (n = 1) and adult respiratory distress syndrome (n = 1). No complications or technical difficulties were observed during catheter insertion. In two cases, the second determination of CCO was not obtained because of complete block heart after ice-boluses (inferior myocardial infarction) and, in one case, the catheter was displaced after BCO determinations gave an aberrant CCO value. Data obtained by BCO ranged from 2.46 to 11.20 L·min^{-1} (mean 6.40 L·min^{-1}) and those obtained by CCO ranged from 1.75 to 10.05 L·min^{-1} (mean 6.40 L·min^{-1}).

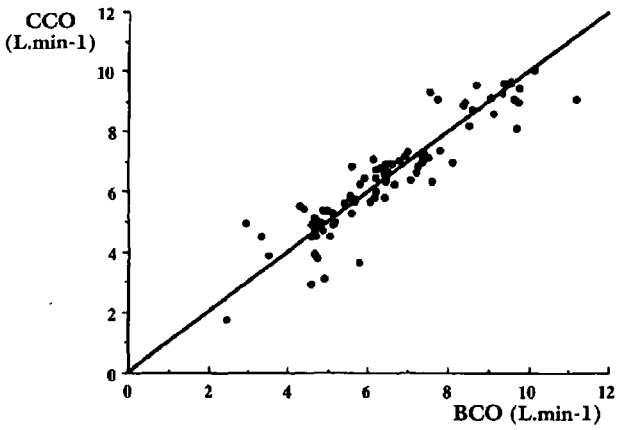

FIGURE 1 Comparison between conventional ice-bolus cardiac output (BCO) and semi-continuous cardiac output (CCO) determination. Paired data were plotted and the line of equality was drawn.

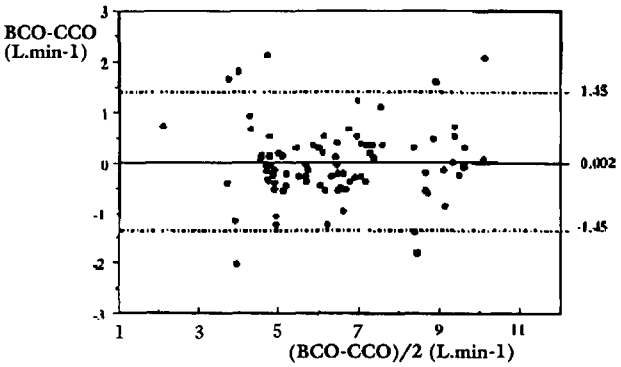

FIGURE 2 Agreement between BCO and CCO methods. Bias (mean difference) was plotted against the mean value of BCO plus CCO. Bias was 0.002 L·min^{-1}. Precision (SD of the bias) was 0.74 L·min^{-1}. *Broken lines,* limits of agreement (bias ± 1.96 SD). *Solid lines,* bias.

Agreement

The equality line is shown in Figure 1. Bias was 0.002 L·min^{-1}, precision was 0.74 L·min^{-1} and the limits of agreement ranged from -1.45 to 1.45 L·min^{-1} (Figure 2).

Reproducibility

Reproducibility was analysed for 90 BCO and 87 CCO and was 0.18 and 0.155 L·min^{-1} respectively. Therefore, the threshold required to consider two

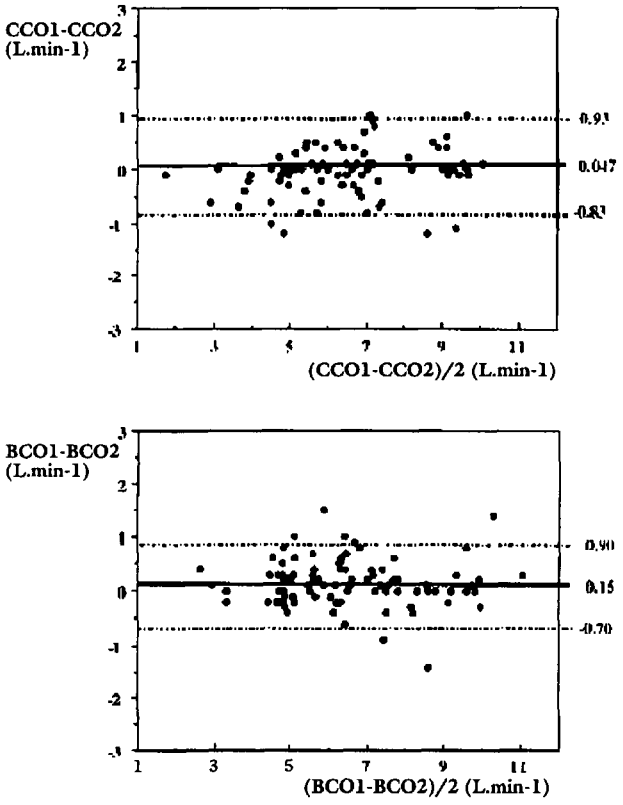

FIGURE 3 Upper graph: reproducibility of the bolus cardiac output determination (BCO). *Broken lines,* limits of agreement (bias ± 1.96 SD). *Solid lines,* bias. Lower graph: reproducibility of the semi-continous cardiac output determination (CCO). *Broken lines,* limits of agreement (bias ± 1.96 SD). *Solid lines,* bias.

measurements as different (3 × SEM) were 0.54 L·min^{-1} for BCO and 0.465 L·min^{-1} for CCO. Analysis, acording to Bland and Altman, showed negligible bias (0.047 L·min^{-1}) for CCO reproducibility (Figure 3) which was not different from the ideal null bias ($P > 0.10$). For BCO reproducibility, the bias was 0.15 L·min^{-1} and different of the null bias ($P = 0.01$).

Discussion

The main results of this study are the following. First, comparison of BCO with CCO showed null bias and limits of agreement > one L·min^{-1}. If this new procedure is accurate, it cannot be considered as interchangeable with BCO. Secondly, reproducibility of the two methods of measurements was not equivalent: repeated measurements of BCO were more variable than those of CCO.

Two systems of semi-continuous CO determination, based on the same principle of thermodilution with heat bolus are now available (Intellicath™ and vigilance™ Baxter-system and Opti-Q™ and Q-vue™ Abbott-system). The Baxter-CCO system has been evaluated largely in the ICU and, when compared with BCO, most studies have shown large limits of agreement suggesting that the two methods are not interchangeable (Table).[5-8,13,14] Monchi *et al.* have evaluated the Abbott-system in 10 critically ill patients.[16] The bias was 0.28 L·min^{-1}, precision was 1.0 L·min^{-1} and the limits of agreement ranged between -1.68 to 2.24 L·min^{-1}. They concluded that precision of the method was sufficient for ICU clinical practice. Nevertheless, they did not assume that both methods were interchangeable. In our study, we found a better accuracy with a bias of 0.002 L·min^{-1} and a precision of 0.74 L·min^{-1}.

The most important differences between the Baxter-system and the Abbott-system are modality of heat delivery (stochastic *vs* binary), energy of the thermal filament (300 Watts·sec^{-1} *vs* 240 Watts·sec^{-1}) and length (10 cm *vs* 15 cm), computational treatment of the input-output signal, and the possibility for the Abbott-system to verify the correct position of the thermal filament with the DTTP™. Thus, it was important to evaluate the more recently available sys-

TABLE Studies comparing conventional bolus cardiac output (BCO) with Baxter / semi-continuous cardiac output (CCO) in intensive care units (ICU).

Reference	n patients	Samples (L·min^{-1})	CCO Range (L·min^{-1})	Bias (L·min^{-1})	Precision (L·min^{-1})	Limits of agreement
Yelderman, 1992[13]	54	222	2.8 - 10.8	0.02	0.54	-1.04 to 1.08
Munro, 1994[5]	9	100	5.5 - 14.0	0.02	0.88	-1.70 to 1.74
Boldt, 1994[14]	35	404	1.6 - 16.0	0.52	0.52	- 0.99 to 1.05
Haller, 1995[6]	14	163	3.8 - 15.6	0.35	1.01	- 1.63 to 2.32
Lefranc, 1995[7]	19	105	2.1 - 17.8	- 0.8	1.22	- 3.2 to 1.6
Le Tulzo,1996[8]	23	369	2.8 - 16.0	- 0.39	0.85	- 2.06 to 1.28

Bias is the mean difference (MD) between the two thechniques of CO measurement. Precision is the standard deviation (SD) of this difference. Limits of agreement are defined as MD ± 1.96 SD.

tem to test its accuracy and reproducibility compared with BCO, which is considered as the gold standard despite reported drawbacks.[15]

To assess the agreement between BCO and CCO we used Bland and Altman analysis, since the correlation coefficient measures only the strength of relation between two variables and not the agreement between them.[9,10] The second step was to study the reproducibility of BCO and CCO, since this parameter could limit the amount of agreement.[10] As pointed out by Bland and Altman[9,10] "When the old method is the more variable one, even a new method that is perfect will not agree with it". Two statistical analyses were performed and allowed different information about reproducibility. The SEM provides a value which defines two consecutive CO measurements as different.[11] The calculation of bias is another method to test the reproducibility. Bias, the mean difference of two consecutive values of BCO and CCO, must be ideally equal to zero if the technique of measurement is highly reproducible.[10]

Determination of the threshold of clinical relevance to define two methods of measurement as interchangeable is difficult to assess. In 17 patients, Matthew *et al.* have compared two computers of BCO determination. They found that one computer systematicaly provided a CO which was 0.77 $L \cdot min^{-1}$ higher than the other.[17] Carpenter *et al.* reported BCO standard deviation to be as large as 0.18 $L \cdot min^{-1}$ to 2.14 $L \cdot min^{-1}$ in six ICU patients, while that of the Fick method ranged from 0.04 $\cdot .min^{-1}$ to 0.35 $L \cdot min^{-1}$.[18] Stetz *et al.* analysed nine studies which compared ice-bolus thermodilution with Fick or indicator methods of CO determination.[11] Before concluding that there was a significant change in two consecutive determinations of cardiac output, they recommended a minimum variation of 13% and at least 22% when BCO was performed in triplicate and unique injection, respectively. Ideally, the threshold of clinical relevance should be defined in advance to help in the interpretation of the method comparison.[10] We selected, as limits of clinical relevance, a threshold of ± 1$L \cdot min^{-1}$. Above these limits the methods cannot be considered to be interchangeable. Indeed, it is difficult to consider that differences as large as -1.45 to 1.45 $L \cdot min^{-1}$ found in our study or -1.64 to 2.24 $L \cdot min^{-1}$ in the study conducted by Monchi *et al.* are negligible despite the variability of the BCO method.[16] These differences may be acceptable in clinical practice in regard to this variability, but it is not possible to consider the two methods as interchangeable.

As specified above, reproducibility is a parameter which may explain lack of agreement. We have previously shown that the high reproducibility of the Baxter-system compared with BCO could explain the lack of agreement between the two techniques.[8] Indeed, in this previous study, the limits of agreement were -2.46 to 1.28 $L \cdot min^{-1}$ and reproducibility evaluated by the calculation of the SEM was two-fold higher for BCO than for CCO (0.25 and 0.13 $L \cdot min^{-1}$ respectively).[8] In the present study, the reproducibility of the two techniques was nearly equivalent (0.18 $L \cdot min^{-1}$ for BCO *vs* 0.155 $L \cdot min^{-1}$ for CCO). Nevertheless, the CCO repeatability estimated by the method of Bland and Altman [9] was superior to that for BCO (0.15 $L \cdot min^{-1}$, $P < 0.05$ and 0.047 $L \cdot min^{-1}$, $P > 0.1$ respectively). It is noteworthy that the reproducibility of the BCO Abbott-system was high, compared with that found by Le Tulzo *et al.*[8] with the Baxter-system (0,18 $L \cdot min^{-1}$ *vs* 0.25 $L \cdot min^{-1}$ respectively). Moreover, reproducibity of both CCO systems appeared equivalent (0.13 $L \cdot min^{-1}$ for Baxter-system and 0.155 $L \cdot min^{-1}$ for Abbott-system).

The clinical application of semi-continuous cardiac output monitoring in the Intensive Care Unit is large. It provides continuous information and, thus, may dramatically warn about CO variation. Moreover, there is no fluid loading, deleterious in patients with anuric acute renal failure or pulmonary oedema, and fewer manipulations of the catheter could decrease associated infections. Lastly, it is time saving for physicians or nurses who performed CO. In this regard, we have calculated the mean time to determine three consecutive BCO, including hand-washing before and after the procedure, and found that six minutes 30 seconds were necessary. With hourly determinations, near three hours are daily used for this activity.

Compared with classic pulmonary artery catheter, there are no limitations to this technique except the inability of the monitor to perform CO measurement when core body temperature exceeds 40C. Indeed, the upper temperature of the thermal filament is limited to 44C and a minimal difference of 4C is necessary to detect a significant change in blood temperature.

In conclusion, the new system of semi-continuous cardiac output measurement (OptiQ™and Q-vue™ Abbott system) is acceptable in clinical practice but cannot be considered as interchangeable with BCO determination. Reproducibility of CCO was superior to BCO.

References

1 *Connors AF Jr, McCaffree DR, Gray BA.* Evaluation of right-heart catheterization in the critically ill patient without myocardial infarction. N Engl J Med 1983; 308: 263–67.

2 *Rao TLK, Jacobs KH, El-Etr AA.* Reinfarction following anesthesia in patients with myocardial infarction. Anesthesiology 1983; 59: 499–505.
3 *Shoemaker WC, Appel PL, Waxman K, Swartz S, Chang P.* Clinical trial of survivors' cardiorespiratory patterns as therapeutic goals in critically ill postoperative patients. Crit Care Med 1982; 10: 398–403.
4 *Tuchschmidt J, Fried J, Astiz M, Rackow E.* Elevation of cardiac output and oxygen delivery improves outcome in septic shock. Chest 1992; 102: 216–20.
5 *Munro HM, Wood CE, Taylor BL, Smith GB.* Continuous invasive cardiac output monitoring - the Baxter/Edwards Critical-Care *Swan Ganz® Intellicath™* and *Vigilance™* system. Clin Intensive Care 1994; 5: 52–5.
6 *Haller M, Zöllner C, Briegel J, Forst H.* Evaluation of a new continuous thermodilution cardiac output monitor in critically ill patients: a prospective criterion standard study. Crit Care Med 1995; 23: 860–6.
7 *Lefranc J-Y, Bruelle P, Ripart J, et al.* Cardiac ouput measurement in critically ill patients: comparison of continuous and conventional thermodilution techniques. Can J Anaesth 1995; 42: 972–6.
8 *Le Tulzo Y, Belghith M, Seguin P, et al.* Reproducibility of thermodilution cardiac output determination in critically ill patients: comparison between bolus and continuous method. J Clin Monit 1996; 12: 379–85.
9 *Altman DG, Bland JM.* Measurement in medicine: the analysis of method comparison studies. Statistician 1983; 32: 307–17.
10 *Bland JM, Altman DG.* Statistical methods for assessing agreement between two methods of clinical measurement. Lancet 1986; 1: 307–10.
11 *Stetz CW, Miller RG, Kelly GE, Raffin TA.* Reliability of the thermodilution method in the determination of cardiac output in clinical practice. Am Rev Respir Dis 1982; 126: 1001–4.
12 *Le Gall J-R, Lemeshow S, Saulnier F.* A new simplified acute physiology score (SAPS II) based on a European/North American multicenter study. JAMA 1993; 270: 2957–63.
13 *Yelderman ML, Ramsay MA, Quinn MD, Paulsen AW, MacKown RC, Gillman PH.* Continuous thermodilution cardiac output measurement in intensive care unit patients. J Cardiothorac Vasc Anesth 1992; 6: 270–4.
14 *Boldt J, Menges T, Wollbrück M, Hammermann H, Hempelmann G.* Is continuous cardiac output measurement using thermodilution reliable in the critically ill patient? Crit Care Med 1994; 22: 1913–8.
15 *Nishikawa T, Dohi S.* Errors in the measurement of cardiac output by thermodilution. Can J Anaesth 1993; 40: 142–53.
16 *Monchi M, Goldstein J, Bellefant F, Thebert D, Brunet F, Dhainaut JF.* Evaluation du système de monitorage du débit cardiaque par thermodilution Abbott OptiQ. (Abstract) Réanimation Urgences 1996; 5: 785.
17 *Matthew EB, Vender JS.* Comparison of thermodilution cardiac output measured by different computers (Letter). Crit Care Med 1987; 15: 989.
18 *Carpenter JP, Nair S, Staw I.* Cardiac ouput determination: thermodilution versus a new computerized Fick method. Crit Care Med 1985; 13: 576–9.