Accuracy assessment for three fiberoptic pulmonary artery catheters for $S\bar{o}_2$ monitoring

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Received: 15 April 1993/Accepted: 14 September 1993

Abstract. Objective: To compare values of $S\bar{o}_2$ obtained by reflectance spectrophotometry continuous monitoring with those obtained from blood samples measurements by transmission spectrophotometry (CO-oximetry).

Design: Values of $S\bar{o}_2$ recorded by three pulmonary artery catheters for continuous monitoring, SAT1, SAT2 and Oximetrix3 (OX3), were compared in a prospective manner to those measured on blood samples by a Co-Oximeter, using the statistical analysis of Bland and Altman.

Setting: Adult intensive care unit in an University Hospital.

Patients: 37 patients admitted for acute respiratory failure and/or shock who required hemodynamic monitoring.

Main results: The bias (average under- or overestimation) was small for all comparative measurements: +1.3, -0.2 and +1.0 sat% for SAT1, SAT2 and OX3, respectively. However, limits of agreement were only acceptable for SAT2 (-8.3 to +7.9 sat%) and OX3 (-6.7 to +8.6 sat%), but not for SAT1 (-23.3 to +25.9 sat%). No significant drift during 24 h was found with the three catheters. However, in vitro calibration was only found acceptable for SAT2 and OX3. The results were not influenced by the numbers of wavelengths of the device (2 for SAT1 and SAT2, and 3 for OX3) nor did they correlate with any of the hemodynamic and biochemical variables tested.

Conclusion: For usual monitoring in the ICU, SAT2 and OX3, gave $S\bar{o}_2$ values which are in acceptable agreement with $S\bar{o}_2$ measured on blood samples by CO-oximetry.

Key words: $S\bar{o}_2$, $S\bar{o}_2$ monitoring – Fiberoptic – Pulmonary artery catheters

Introduction

Hemoglobin saturation of mixed venous blood ($S\bar{o}_2$) reflects the total body balance between oxygen delivery and oxygen consumption of perfused tissues. Initial attempts to apply spectrophotometric techniques for $S\bar{o}_2$ monitoring had met with limited success [1-4]. Nevertheless, it was possible to overcome many of the technical problems by use of pulmonary artery catheters with incorporated fiberoptics, light emitting diodes, and multiple reference light wavelengths. These features were thus incorporated into several systems of fiberoptic reflectance spectrophotometry for bedside $S\bar{o}_2$ monitoring.

Although potentially useful for the management of critically ill patients [5], the accuracy of these devices still remains a matter of controversy [6-10]. In an animal study of 6 to 10 hrs duration, Gettinger et al. [6] found that a three wavelength system (OX3) was more accurate than a two wavelength one (SAT1), a finding not reproduced by Reinhart et al. [7] during long term use of the same catheters in critically ill patients. Recent reports seem to suggest that the OX3 using a three wavelength catheter system is the most accurate [8-10].

In all these studies, including a recent one [11], authors have made use of correlation coefficients to determine the agreement between methods measuring the same variable. However, conclusions drawn from such analysis might be misleading, resulting in inappropriate rejection or acceptance of a new device [12-13]. The statistical analysis of Bland and Altman [14] is the appropriate method to evaluate the agreement between two methods.

The purposes of the present study were: (i) to evaluate the agreement between $S\bar{o}_2$ recorded by three catheter systems (CATH systems), i.e. SAT1, SAT2 and Oximetrix (OX3) and $S\bar{o}_2$ measured on blood samples with a Cooximeter (CO-$S\bar{o}_2$); (ii) to evaluate the drift of these systems over 24 h; (iii) to investigate the influence of some hemodynamic or biochemical factors on the agreement, as suggested by previous studies [7, 15]. There is, to our knowledge, only one recent study by Scuderi et al.
who used an appropriate statistical method of analysis and provided data on SAT2.

Material and methods

Thirty seven critically ill patients (mean age: 62.5 ± 13 years), requiring hemodynamic monitoring, were prospectively enrolled into the present study. These patients were admitted to the Intensive Care Unit of Cochin Port-Royal University Hospital in Paris for acute respiratory failure and/or shock. One of the following fiberoptic pulmonary artery catheters, SAT1, SAT2 (Baxter Health Care Corp., Santa Aaa, CA) or OX3 (Oximexrix, Abbott Critical Care Systems, North Chicago, IL) was inserted at random in 8, 15 and 14 patients, respectively. The SAT1 catheter was withdrawn from the market during the study period. SAT1 and SAT2 use a two wavelength systems whereas OX3 relies on a three wavelengths system. The study protocol was approved by the Institutional Review Board.

Calibration

Each catheter was calibrated in vitro, prior to fluid flush within the sterile container provided with the product packaging, according to the manufacturer’s instructions. Catheters were then percutaneously inserted through the right or left internal jugular vein. Adequate positioning of the catheter in the pulmonary artery was deemed when the characteristic wave forms of pulmonary arterial pressure and capillary wedge pressure were obtained. Control of the catheter position by chest X-ray was made immediately after insertion, then daily or when a dislocation was suspected. Similarly, in vivo calibration was performed by entering the value of CO-S\textsubscript{02} measured on a blood sample immediately after insertion and then at 9:00 a.m. daily. At the same time, the patient’s hematocrit value and hemoglobin concentration were updated in the Edwards computers (SAT1 and SAT2 systems), whereas this was not needed for OX3 system. Hemoglobin concentration and CO-S\textsubscript{02} were measured with a Hemocritometer (OSM2, Radiometer, Copenhagen, Denmark) calibrated each day with known standards. No patient was receiving intralipid emulsion which could lead to erroneous measurements of S\textsubscript{02}. Pulmonary artery catheters were left in place as long as it was thought medically necessary (3 ± 0.8 days).

Agreement between catheters (CATH) and co-oximeter (CO)-S\textsubscript{02} measurements

This protocol was designed to evaluate the agreement between intravascular monitoring and blood samples measurements performed whenever considered clinically necessary, i.e. when marked changes in either heart rate, blood pressure, pulmonary artery occluded pressure, or Sa\textsubscript{02} occurred. Mixed venous samples were collected anaerobically into 2 ml heparinized syringes, after the clearance of the catheter dead space. Each blood sample was slowly drawn (2 ml in 30 s to 45 s) to avoid possible contamination with capillarized blood. A total of 51, 106 and 77 comparative measurements of S\textsubscript{02} were performed between the SAT1, the SAT2 and OX3 CATH-Systems respectively, and the Co-Oximeter. Finally, 234 sets of data were obtained making an average of 6.3 sets per patient and a range from 1 to 4 sets per patient per day.

In addition, we tested the agreement between CATH- and CO-S\textsubscript{02} immediately after insertion to evaluate the reliability of the in vitro calibration performed before insertion. This latter couple of data was also used as the first in vivo calibration. To evaluate the drift of each CATH-system, we also checked the agreement between CATH and CO-S\textsubscript{02} measurements 24 h after the first in vivo calibration.

Influence of hemodynamic and biochemical variables

Only spontaneous variations were measured and taken into account in this study. Hemodynamic factors tested included: heart rate, cardiac output, mean pulmonary artery pressure, pulmonary artery occlusion pressure and Fick-derived oxygen consumption. Mixed venous blood variables, pH and PCO\textsubscript{2} were measured on the same sample as CO-S\textsubscript{02}. These measurements were made with a blood gas analyzer (178 Corning, Medfield, MA) automatically calibrated with one and two known standards every hour and every 2 h respectively. Peripheral venous blood variables tested included: hemoglobin, hematocrit, proteins, sodium, bilirubin and four erythrocyte corpuscular variables, i.e. mean corpuscular hemoglobin concentration (MCHC), mean corpuscular hemoglobin (MCH), mean corpuscular volume (MCV) and red cell distribution width (RCDW). The corresponding measurements were performed with routine blood laboratory techniques. We did not measure methemoglobin and CO-hemoglobin because these variables were not likely to change widely in critically ill patients [8].

Statistical analysis

The agreement between CATH- and CO-S\textsubscript{02} measurements was evaluated by the method of Bland and Altman [14]. According to this method, 2 types of diagrams were drawn. First, we plotted the paired data and drew the line of identity on which all points would lie if the two methods gave exactly the same results every time (Fig. 1, left). This provided a rough estimation of the degree of agreement between measurements. Second, the difference between the two methods was plotted against their mean (Fig. 1, right), because the mean of the two measurements was the best estimate of the true value. The degree of agreement was summarized by calculating the bias or mean of the differences (MD) and the standard deviation of the difference (SD). If differences within the limits of agreement, i.e. MD ± 2SD, were not clinically relevant, the two methods are interchangeable. According to Nelson [5], we considered that a change in S\textsubscript{02} is likely to be of clinical relevance if it exceeds ± 10 sat%, and this threshold was used to interpret our results.

Evaluation of the repeatability of the 2 methods, as recommended by Bland and Altman, was not possible because continuous intravascular measurements do not allow repeated measurements in exactly the same conditions.

To determine if the differences in S\textsubscript{02} by the 2 methods (CATH vs co-oximeter) were influenced by the hemodynamic or biochemical factors, we used parametric (linear regression) or non parametric (Spearman rank test) correlations, depending on whether or not the data were normally distributed. According to Bonferroni’s correction, p < 0.005 was considered significant.

Intergroup comparisons for age, hemodynamic and biochemical data were made with the non parametric Friedman test.

Results

The three CATH-system groups did not significantly differ one from another with regard to age, hemodynamic and biochemical variables. The SAT1 catheter was used for an average of 3.2 ± 0.8 days, the SAT2 for 2.9 ± 0.7 days and the OX3 for 2.9 ± 0.8 days. One SAT1, 3 SAT2 and 2 OX3 catheters had to be replaced because of technical defects detected by light intensity alarms. There was no thermistor defect with the catheters, and balloon rupture occurred only in one SAT2 catheter.

Agreement between CATH- and CO-S\textsubscript{02}

The agreement between paired values recorded by one of the CATH and CO is shown on Fig. 1. Table 1 (Part A) summarizes these results in terms of MD (mean difference) and ± 2SD (standard deviation of the differences). MD was + 1.3, − 0.2 and + 1.0 sat% for SAT1, SAT2 and OX3, respectively. The limits of agreement (i.e. MD ± 2SD to MD ± SD) were − 23.3 to + 25.9 sat%, − 8.3 to + 7.9 sat% and − 6.7 to + 8.6 sat% for SAT1, SAT2 and OX3, respectively. In other words, the mean difference shows that none of the CATH-systems systematically over- or underestimated the S\textsubscript{02} (MD ≤ 1.3 sat%).