Accuracy and Precision of Masimo SET, Agilent Merlin, and Nellcor N-395 Pulse Oximeters in Patients Undergoing Cardiopulmonary Bypass for Congenital Heart Defects.


Introduction

Patients undergoing congenital heart repair requiring cardiopulmonary bypass (CPB) frequently experience saturations below 90%. Pulse oximetry has become an integral part of perioperative management of these patients but in situations of poor peripheral perfusion or severe oxygen desaturation, accuracy and reliability are questionable. The aim of this study was to compare the accuracy of three pulse oximeters with reported improved capabilities, Masimo SET, Agilent Merlin, and Nellcor N-395 in these patients.

Methods

Following IRB approval and informed consent, patients between the ages of 1 day to 53 years scheduled to undergo surgery for congenital heart disease requiring CPB were enrolled. Immediately after unconsciousness, three pulse oximeters (Masimo SET, Agilent Merlin and Nellcor N-395) were attached to specified digits on a rotational basis to avoid bias regarding arterial and venous catheter location. Probes were shielded by black tape on each digit to avoid light interference and sensor to sensor optical cross-talk. Pulse oximeter derived oxygen saturations (SpO2) and pulse rate were recorded and stored each second in a dedicated computer. A CO-Oximeter was used to determine arterial oxygen saturation (SaO2) to compare with SpO2 values at the following points: baseline (after induction), 10 minutes after protamine administration, sternal closure, 30 minutes after intensive care unit (ICU) arrival and 30 minutes post extubation. Agreement between SpO2 and SaO2 was assessed for each oximeter using the methods of Bland and Altman. In all cases p-values d’0.05 denoted statistical significance.

Results

Fifty-two patients were studied. Demographics and surgical characteristics are in the table. The median age was 2 years. Forty of the 52 patients (77%) had a period of circulatory arrest. Bland-Altman plots, showing the agreement between saturation measured by pulse oximetry and by CO-Oximetry is presented in the figure. Separate analyses were also performed for three groups defined using SaO2 (>90%, 80%-90%, <80%). To assess whether the loss of measurement precision observed at low levels of SaO2 differed significantly between pulse oximeters, a repeated measures analysis of covariance was employed. The bias ± precision of the Masimo SET, Agilent Merlin and Nellcor N-395 were -3.0±2.5, 0.0±2.7 and 0.0±2.8 at SaO2 >90%; -2.1±4.2, -2.4±8.0 and -1.3±5.2 and at 80% SaO2 ≤90% (p<0.05), and 3.5±6.0, 3.6±14.1 and 3.6±8.4 at SaO2 < 80% respectively.

Discussion

Findings demonstrate that the Masimo SET pulse oximeter has better precision than the Agilent and Nellcor oximeters when saturation is between 80% and 90% in patients undergoing cardiac surgery requiring CPB for congenital heart defects. Because our study was unable to obtain much information regarding saturations below 80%, additional studies need to be performed to access accuracy in this range.