

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

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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.¹ 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.² In all cases p-values <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 assess accuracy in this range.