The Accuracy of Masimo SET and Nellcor N-595 in Children with Cyanotic Congenital Heart Disease.

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Background

Pulse oximetry is a standard monitoring tool for patients in intensive care unit and operating theater. Especially, this technology is indispensable when caring pediatric patients with congenital heart disease (CHD). However, relative inaccuracy of pulse oximetry in patients with cyanotic CHD has been recognized. Furthermore, the inaccuracy of measurement could be apparent when peripheral perfusion is insufficient such as early after cardiac surgery. During this period, saturation measurement is crucial in patients with complex cyanotic CHD. The Blue Sensor probe developed by Masimo is specifically designed for use in patients with low saturations. This probe also provides perfusion index (PI) which appears on the display area of Masimo SET. PI is considered as a signal to determine how well tissue is perfused at the measurement site of pulse oximetry. This observational study is designed to assess accuracy of Blue Sensor when comparing with Nellcor sensor, especially when decreased tissue perfusion.

Methods

Seven pediatric patients with cyanotic CHD either in intensive care unit or operating theater were enrolled. Measurement of SaO2 of blood sample from arterial line were compared with simultaneous pulse oximetry saturations (SpO2) obtained from both Masimo Blue Sensor and Nellcor N-595 Oximax Max-I sensor. PI was also recorded simultaneously. Data analysis includes linear regression between SaO2 and SpO2 and bias comparison. Bias were compared between Masimo and Nellcor sensors and then data were divided into two groups; low PI (<1.2) and normal PI (>=1.2) for each sensor as median PI was 1.2. A t-test was used to compare the bias and $p<0.05$ was considered statistically significant.

Results

Seven patients were studied and their mean age and body weight were 16 months (range; 1-31 months) and 7.0 kg (range; 4.7-13.4 kg), respectively. A total of 39 SaO2 measurements were recorded. Both sensors presented strong linear correlation (Masimo R2=0.90, P<0.0001 vs Nellcor R2=0.75, P<0.0001). However, Masimo blue sensor presented smaller bias compared with Nellcor sensor (table1, Fig1). Moreover, Nellcor presented wider bias during low perfused state than that at normal perfusion.

Bias of Masimo SET Blue Sensor and Nellcor N-595 OxiMax MAX-I

	Bias-Masimo (95%CI)	Bias-Nellcor (95%CI)	*P* value
Overall	0.14 (-0.63 to 0.90)	-2.56 (-3.73 to -1.38)	0.0006
PI<1.2	-0.17 (-1.43 to 1.10)	-3.67 (-5.42 to -1.92)	0.0065
PI>=1.2	0.45 (-0.50 to 1.41)	-1.39 (-2.92 to 0.15)	0.0421

P value for comparison between Bias-Masimo and Bias-Nellcor. Bias-Nellcor was significantly different between PI<1.2 and PI>=1.2 (P=0.043) but Bias-Masimo not.

Conclusion

Masimo blue sensor provides the accurate measurement of pulse oximetry in patients with cyanotic CHD. This measurement was secured in case tissue is not well perfused.