Original Article

Accuracy of In-Line Venous Saturation and Hematocrit Monitors in Pediatric Perfusion

Scott M. Yaskulka, BS; Jeff Burnside, BS, CCP*; Denise Bennett, BS, CPT*; Vince Olshove, BS, CCT*; Jim Langwell, CPT*

Division of Circulation Technology, School of Allied Medical Professions, The Ohio State University, and *Columbus Children's Hospital, Department of Cardiovascular Perfusion, Columbus, Ohio

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ABSTRACT

Cardiopulmonary bypass (CPB) in neonates and infants routinely employs lower blood flow rates (BFR), temperatures, and hematocrits (Hct) than those typically observed in adult CPB. The purpose of this study was to evaluate the accuracy of three devices available for continuous in-line measurement of venous oxygen saturation (SvO_2) and Hct during pediatric CPB.

Venous blood samples were obtained over a range of BFR, temperatures, and Hct and analyzed on a Corning 2500 Co-Oximeter and HematoStat C-70 centrifuge. These values were then compared to those measured by the Bentley OxySat SM-0200, the Gish StatSat, and the 3M CDI 100 in-line monitors.

Seventy samples were obtained and analyzed using linear regression, paired t-test and residual analysis to establish the reliability and accuracy of each device. The results demonstrate the CDI to be more statistically accurate ($p > 0.05$) than the Gish and Bentley devices for measuring SvO_2 in nearly all circumstances, though all correlated well with the control ($r > 0.70$). When comparing spun Hct to the CDI and Gish values, the CDI in-line monitor demonstrated a greater reliability to predict actual patient Hct ($r > 0.90$) than the Gish StatSat ($r > 0.60$). Residual analysis revealed that even though the Gish StatSat had higher calculated p values ($p > 0.05$) than the CDI 100 for interpreting Hct, it was shown to display more inconsistent and sporadic values over the ranges of BFR and temperature studied. It is concluded that the CDI 100 proved to be more accurate, reliable, and consistent than the Gish StatSat and the Bentley Oxysat devices in determining SvO_2 and Hct over all evaluated parameters in this study.

Address correspondence to:
Scott M. Yaskulka
Charleston Area Medical Center
Memorial Division
Perfusion Department
3200 MacCorkle Avenue, SE
Charleston, West Virginia 25304

INTRODUCTION

One of the goals of extracorporeal circulation is to provide proper oxygenation to meet the metabolic demands of the patient. Venous oxygen saturation (SvO_2) and hematocrit (Hct) are two parameters which help evaluate the adequacy of tissue oxygenation (1,2). There are several in-line devices available that will provide this information on a continuous basis. Although these monitors have been shown to be reliable trending devices in adult cardiopulmonary bypass (CPB) (3), little information is available regarding their reliability for use in pediatric CPB. Pediatric CPB can be a rigorous test for these devices due to the extremely low ranges in blood flow rate (BFR), temperature, and Hct (4).

The purpose of this study was to evaluate three continuous, in-line Hct and/or SvO_2 monitors against BFR, temperature, and Hct to determine their clinical reliability and accuracy in determining SvO_2 and Hct for use during pediatric CPB procedures.

MATERIALS AND METHODS

A total of seventy venous blood samples were drawn during periods of deep, moderate/mild, and normothermic phases of pediatric CPB. The samples were drawn only after the monitors displayed a constant readout for several minutes. The monitor readouts, venous blood temperature, and CPB BFR were recorded as the blood was drawn from the circuit. The samples then were analyzed for SvO_2 and Hct using a clinically accepted seven wavelength Co-Oximeter[a] and a micro-centrifuge[b], respectively. The time delay between sampling and analysis was kept to under five minutes in all cases. The monitors that were independently evaluated included the Bentley OxySat[c], the Gish StatSat[d], and the CDI 100[e] (Table 1).

Cuvettes from the three Hct and/or Sat monitors were inserted into the venous line of the extracorporeal circuit in a consistent order and location between the patient and the venous reservoir for every case used in this study.

The 1/4" cuvettes were inserted for patients requiring less than 1.5 L/min BFR, and the 3/8"cuvettes for patients requiring a BFR greater than 1.5 L/min. The data points obtained were sorted by BFR and temperatures that were recorded at the time the samples were drawn, as well as the Hct of the sample from micro-centrifuge measurements. These values were then analyzed using paired t-tests, linear regression, and residual analysis to evaluate the accuracy and reliability of each instrument. The paired t-test was used to reveal if each of the monitor's readings was significantly different from the clinically accepted controls, while linear regression was used to display any correlation between the readouts and the clinical standards. A p value of $p < 0.05$ was considered statistically significant. Residual analysis was used to display the spread of data points about an absolute agreement line (zero line) to determine and analyze any observable trends against CPB variables.

RESULTS

The results of the correlation analysis and the paired t-tests are shown in Tables 2 and 3. The results reveal that at the various BFRs, Hcts, and temperatures, all the monitors displayed a positive correlation with the Co-Oximeter ($r > 0.70$) (Table 2). The paired t-tests for each individual monitor show the CDI 100 to be statistically accurate ($p > 0.05$) over all the evaluated parameters except for the variable of Hct greater than 22%, where it displayed a statistically significant difference ($p = 0.0003$) (Table 2). The Gish StatSat depicted a significant statistical difference ($p < 0.003$) in all categories studied (Table 2). The Bentley OxySat also displayed a significant statistical difference over all parameters ($p < 0.002$) except in the range of temperatures less than 25° C, where it displayed statistical accuracy ($p > 0.05$) (Table 2).

The ability to reliably estimate Hct was exhibited by the CDI 100 as it yielded a high positive correlation ($r>0.90$) (Table 3) with the spun Hct measurements. The Gish StatSat, moreover, produced lower correlation coefficients ($r>0.60$) when compared to the spun Hct measurements over the evaluated parameters (Table 3). These high correlation coefficients suggest that both monitors were reliable in estimating Hct.

The paired t-test demonstrated the Gish device to accurately

a Ciba-Corning 2500, Ciba-Corning Diagnostic Corp., Medfield, MA 02052.
b Hematostat C-70, Separation Technology Inc., Salt Lake City, UT 84119.
c Baxter Healthcare Corp., Bentley Division, Irvine, CA 92704.
d Gish Biomedical Inc., Santa Ana, CA 28226.
e CDI, 3M Health Care, Tustin, CA 92680.

Table 1: Monitors Evaluated

Monitors Evaluated	Mode of Operation	Manufacturers Recomended Operation Specifications		
		Minimum BFR	Sat Range	Hct Range
Bentley OxySat	Dual Wavelength with optical reflectance	25 ml/min	30 - 100%	15 - 40%
Gish StatSat	Three Wavelength with optical reflectance	100 ml/min	45 - 100%	16 - 32%
CDI 100	Three Wavelength with optical reflectance	100 ml/min	60 - 100%	15 - 45%

Table 2: Comparison of SvO_2 Readings for CDI 100, Gish Stat Sat, and Bentley OxySat versus Co-Oximeter

Monitor	Parameters	n	Correlation (r)	t-test p value
CDI 100	BFR < 1000 ml/min	47	0.95	NS
	BFR > 1000 ml/min	23	0.95	NS
	Hct < 22%	14	0.99	NS
	Hct = 22-30 %	31	0.94	NS
	Hct > 22%	25	0.98	0.0003
	Temperature < 25C	19	0.9	NS
	Temperature = 25-32C	25	0.94	NS
	Temperature > 25C	26	0.93	NS
Gish StatSat	BFR < 1000 ml/min	47	0.88	<.0001
	BFR > 1000 ml/min	23	0.96	<.0001
	Hct < 22%	14	0.94	0.003
	Hct = 22-30 %	31	0.9	<.0001
	Hct > 22%	25	0.92	<.0001
	Temperature < 25C	19	0.73	0.007
	Temperature = 25-32C	25	0.86	<.0001
	Temperature > 25C	26	0.86	<.0001
Bentley OxySat	BFR < 1000 ml/min	47	0.95	<0.0001
	BFR > 1000 ml/min	23	0.97	<0.0001
	Hct < 22%	14	0.98	0.003
	Hct = 22-30 %	31	0.96	<0.0001
	Hct > 22%	25	0.97	0.002
	Temperature < 25C	19	0.88	NS
	Temperature = 25-32C	25	0.95	<0.0001
	Temperature > 25C	26	0.96	<0.0001

Key: NS = Not Significant (p > 0.05)

Table 3: Comparison of Hct. Readings

Monitor	Parameters	n	Correlation (r)	t-test p value
CDI 100 Hct	BFR < 1000 ml/min	47	0.97	0.0001
	BFR > 1000 ml/min	23	0.93	0.028
	Temperature < 25C	19	0.98	NS
	Temperature = 25-32C	25	0.92	0.047
	Temperature > 25C	26	0.94	<0.0001
Gish StatSat Hct	BFR < 1000 ml/min	47	0.76	NS
	BFR > 1000 ml/min	23	0.83	0.006
	Temperature < 25C	19	0.89	NS
	Temperature = 25-32C	25	0.75	NS
	Temperature > 25C	26	0.6	NS

Key: NS = Not Significant (p > 0.05)

estimate Hct at all studied parameters when compared to the spun Hct control (p>0.05), except for the range of BFR > 1000 ml/min where a statistical difference was seen (p=0.006) (Table 3). The converse was revealed for the CDI 100, where it appeared to be statistically inaccurate over all the categories of BFR and temperature (p<0.03), except for the range of temperatures less than 25° C where no significant statistical difference was noted.

DISCUSSION

The development of the patient-side and continuous in-line analyzers has provided several methods to insure proper hemodynamic management of a patient undergoing CPB. Analysis that once took several minutes can now be done in an instantaneous, convenient and affordable manner. This can be especially important for pediatric and/or neonatal CPB due to the volatile nature of the oxygen demands caused by the high basal metabolic rate of these patients (5,6).

Individually, results show the CDI 100 and Bentley OxySat to correlate higher with the two controls (against each range of BFR, temperature, and Hct) than the Gish StatSat though all correlation coefficients were statistically accurate in predicting SvO_2 overall. It can be seen in Figures 1-9 that the Gish StatSat and Bentley OxySat monitors tend to underestimate the SvO_2 by values mostly within +10 percent saturation of the zero line (the zero line meaning 100% agreement with the control), whereas the CDI 100 tends to stay mostly within +/- 5 percent saturation about the zero line over all evaluated parameters. This consistency in the readouts can also be seen in the calculated p-values which display a non-significant difference for the CDI 100 in determining SvO_2 over all categories (Table 2). On the other hand, the Gish StatSat's and Bentley OxySat's residuals are more sporadic over all ranges (Figures 2,3,5,6,8,9) suggesting a constant inconsistency in the readouts which makes proper patient

Figure 1

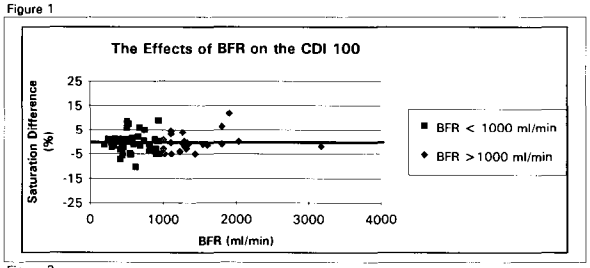


Figure 2

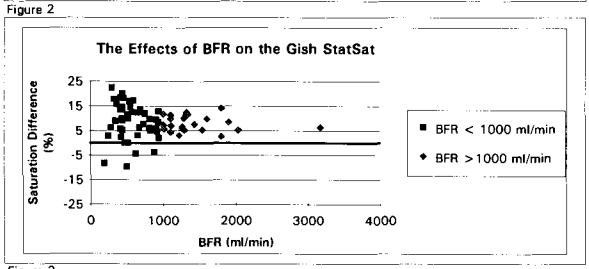


Figure 3

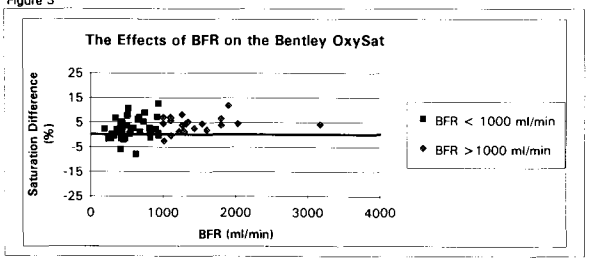


Figure 4

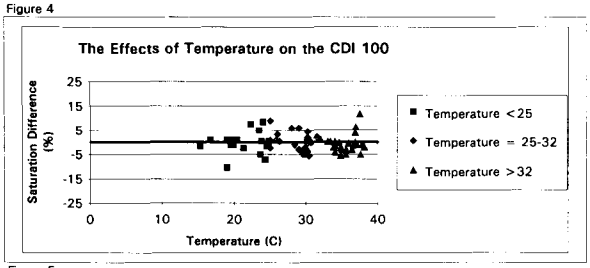


Figure 5

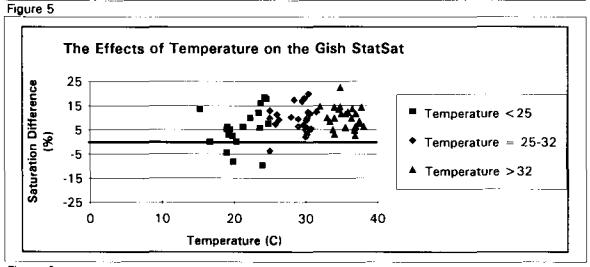


Figure 6

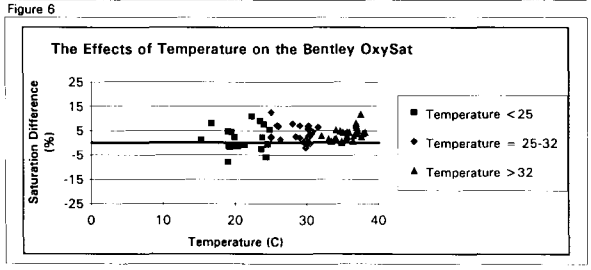


Figure 7

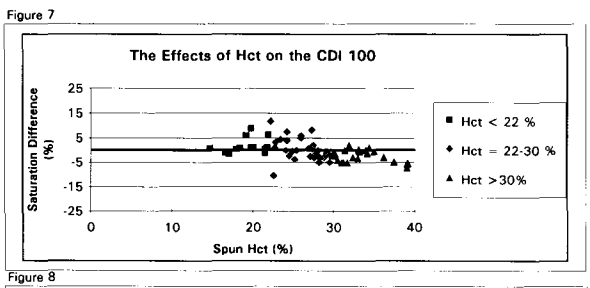


Figure 8

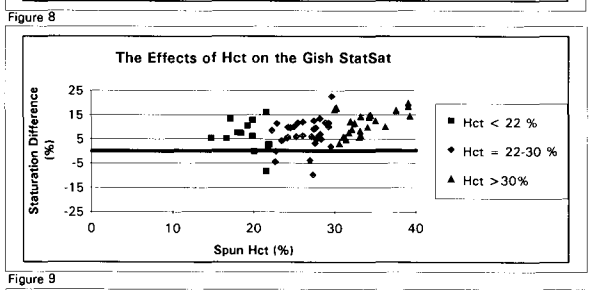


Figure 9

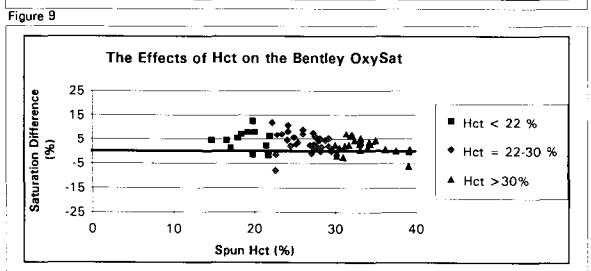


Figure 10

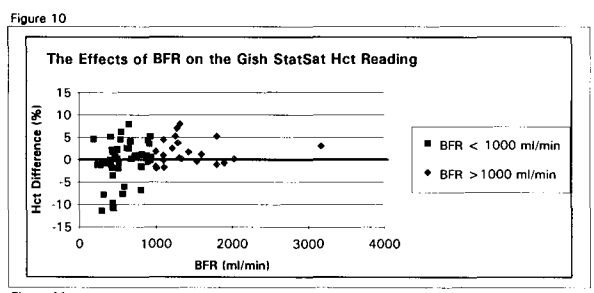
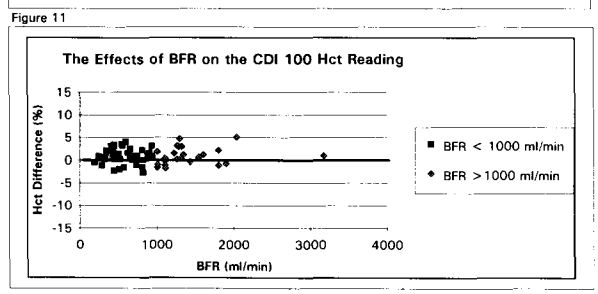


Figure 11



SvO_2 management during CPB more difficult. This fact can be further seen by almost all p-values being less than 0.05 suggesting an overall significant statistical difference for both monitors in relation to the ranges of the evaluated parameters (Table 2).

The ability of the Gish StatSat and CDI 100 to determine an accurate Hct revealed the CDI 100 to correlate higher ($r > 0.90$)

Figure 12

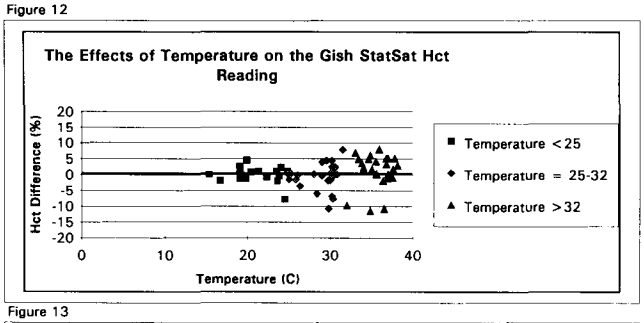
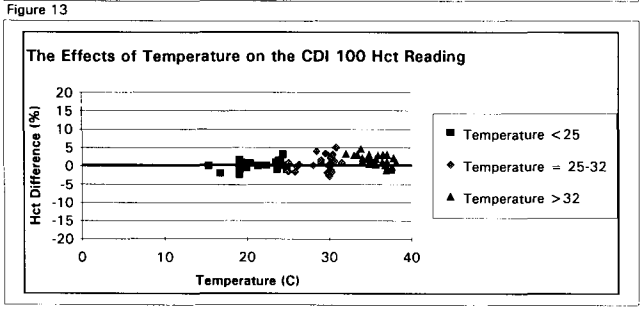


Figure 13



than the Gish StatSat ($r > 0.60$) over the ranges of BFR and temperature (Table 3). Again, this depicts the CDI 100 to be more reliable than the Gish StatSat in registering an appropriate Hct value. However, the t-test results suggest that the Gish StatSat is more accurate since most of its p-values exhibit no significant statistical difference (Table 3). The analysis of the residuals seem to show the opposite. The residual plots reveal that the CDI 100 tended to underestimate the actual Hct but hovers about the zero line within a +/- 5 percent Hct difference with the spun control (Figures 11, 13) over both parameters. The Gish StatSat, conversely, tends to equally over and underestimate the actual Hct within +/- 10 percent Hct difference with the control (Figures 10, 12). This fact may be the reason for the resulting more statistically significant p-value (Table 3) for the Gish StatSat since the data points are equally and evenly distributed about the zero line. This situation causes the values to appear not statistically different.

All three monitors performed well in relation to the various parameters compared to the Co-Oximeter and spun Hct controls. Overall, it was shown that during pediatric CPB, the CDI 100 was more accurate and less affected by changes in BFR, temperature, and Hct than the Gish StatSat and Bentley OxySat, even when the variables approached the minimum specified ranges set by their respective manufacturers.

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