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Pulse Oximetry

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M Masimo-supported Study
A Abstract

** SpHb is not intended to replace laboratory blood testing. Blood samples should be analyzed by laboratory instruments prior to clinical decision making.*

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by Care Area and Patient Population

01: **Pulse Oximetry**

01 Temporal Quantification of Oxygen Saturation Ranges: An Effort to Reduce Hyperoxia in the Neonatal Intensive Care Unit

Bizzarro M.J., Li F.Y., Katz K., Shabanova V., Ehrenkranz R.A., Bhandari V. *J Perinatol*. 2014 Jan;34(1):33–8.

Study Objective

To reduce exposure to hyperoxia and its associated morbidities in preterm neonates.

Study Design

A multidisciplinary group was established to evaluate oxygen exposure in our neonatal intensive care unit. Infants were assigned target saturation ranges and signal extraction technology implemented to temporally quantify achievement of these ranges. The outcomes bronchopulmonary dysplasia/death, retinopathy of prematurity (ROP)/death, severe ROP and ROP requiring surgery were compared in a pre- versus post-intervention evaluation using multivariate analyses.

Results

A total of 304 very low birth weight pre-initiative infants were compared with 396 post-initiative infants. Multivariate analyses revealed decreased odds of severe ROP (adjusted odds ratio (OR): 0.41; 95% confidence interval (CI): 0.24–0.72) and ROP requiring surgery (adjusted OR 0.31; 95% CI: 0.17–0.59) post-initiative. No differences in death were observed.

Multivariate Logistic Regression Analysis for Severe ROP, *N* = 558			
Effect	**Adjusted OR**	**95% CI**	**P-value**
Period (post vs pre)	0.41	0.24, 0.72	0.002
GA (weeks)	0.65	0.52, 0.80	0.0001
BW (100 g)	0.65	0.53, 0.80	<0.0001
Male	1.71	0.98, 2.96	0.06
Race			0.20
Caucasion	1.44	0.82, 2.54	0.20
Asian	0.30	0.03, 2.93	0.30
African American	1.00	—	
Surfactant	4.31	0.97, 19.17	0.06
Pneumothorax	2.76	1.12, 6.83	0.02

Abbreviations: BW, birth weight; CI, confidence interval; GA, gestational age; OR, odds ration; ROP, retinopathy of prematurity.

Conclusion

Significant reductions in severe ROP and ROP requiring surgery were observed after staff education and implementation of new technology to quantify success in achieving targeted saturations and reinforce principles and practices.

02 Pulse Oximetry with Clinical Assessment to Screen for Congenital Heart Disease in Neonates in China: A Prospective Study

Zhao QM, Ma XJ, Ge XL, Liu F, Yan WL, Wu L, Ye M, Liang XC, Zhang J, Gao Y, Jia B, Huang GY; Neonatal Congenital Heart Disease Screening Group. *The Lancet*. 2014. Aug30;384(9945):747-54.

Background

Several pioneering studies have provided evidence for the introduction of universal pulse oximetry screening for critical congenital heart disease. However, whether the benefits of screening reported in studies from high-income countries would translate with similar success to low-income countries is unknown. We assessed the feasibility and reliability of pulse oximetry plus clinical assessment for detection of major congenital heart disease, especially critical congenital heart disease, in China.

Methods

We did a pilot study at three hospitals in Shanghai to assess the accuracy of pulse oximetry plus clinical assessment for detection of congenital heart disease. We made a data collection plan before recruitment. We then undertook a large, prospective, and multicentre screening study in which we screened all consecutive newborn babies (aged 6–72 h) born at 18 hospitals in China between Aug 1, 2011, and Nov 30, 2012. Newborn babies with positive screen results (either an abnormal pulse oximetry or abnormal clinical assessment) were referred for echocardiography within 24 h of screening. We identified false-negative results by clinical follow-up and parents' feedback. We calculated sensitivity, specificity, positive and negative predictive values, and positive and negative likelihood ratios for pulse oximetry alone, and in combination with clinical assessment, for detection of major and critical congenital heart disease.

Findings

In the pilot study, 6785 consecutive newborn babies were screened; 46 of 49 (94%) cases of asymptomatic major congenital heart disease and eight of eight (100%) cases of asymptomatic critical disease were detected by pulse oximetry and clinical assessment. In the prospective multicentre study, we screened 122 738 consecutive newborn babies (120 707 asymptomatic and 2031 symptomatic), and detected congenital heart disease in 1071 (157 critical and 330 major). In asymptomatic newborn babies, the sensitivity of pulse oximetry plus clinical assessment was 93.2% (95% CI 87.9–96.2) for critical congenital heart disease and 90.2% (86.4–93.0) for major disease. The addition of pulse oximetry to clinical assessment improved sensitivity for detection of critical congenital heart disease from 77.4% (95% CI 70.0–83.4) to 93.2% (87.9–96.2). The false-positive rate for detection of critical disease was 2.7% (3298 of 120 392) for clinical assessment alone and 0.3% (394 of 120 561) for pulse oximetry alone.

	N	Detection rate		
		Pulse oximetry alone	Clinical assessment alone	Pulse oximetry plus clinical assessment
Critical pulmonary stenosis	10	10 (100%)	10 (100%)	10 (100%)
Tetralogy of fallot	9	9 (100%)	9 (100%)	9 (100%)
Truncus arteriosus	5	2 (40%)	3 (60%)	4 (80%)
Single ventricle	11	8 (73%)	9 (82%)	10 (91%)
Pulmonary atresia	30	30 (100%)	28 (93%)	30 (100%)
Transposition of great arteries	33	32 (97%)	29 (88%)	32 (97%)
Double outlet of right ventricle	9	8 (89%)	6 (67%)	9 (100%)
Hypoplastic left heart syndrome	7	3 (43%)	2 (29%)	4 (57%)
Critical coarctation of the aorta	7	3 (43%)	4 (57%)	5 (71%)
Interrupted aortic arch	5	2 (40%)	2 (40%)	4 (80%)
Critical aortic stenosis	3	1 (33%)	3 (100%)	3 (100%)
Total anomalous pulmonary venous connection	17	14 (82%)	8 (47%)	16 (94%)
Total	146	84% (122 of 146)	77% (113 of 146)	93% (136 of 146)

Detection rate for individual critical congenital heart disease in asymptomatic newborn babies.

01: Pulse Oximetry – Oxygenation (SpO2), Pulse Rate (PR)

03 Performance of Three New-Generation Pulse Oximeters During Motion and Low Perfusion in Volunteers

Shah N., Ragaswamy H.B., Govindugari K., Estanol L. *J Clin Anesth*. 2012;24(5):385-91.

Study Objective

To evaluate pulse oximeter performance during motion and induced low perfusion in volunteers.

Design: Prospective volunteer study. **Setting:** Direct observation unit. **Subjects:** 10 healthy adult volunteers.

Interventions

Ten volunteers were monitored with 3 different pulse oximeters while they underwent desaturation to about 75% oxygen saturation (SpO2) and performed machine-generated (MG) and volunteer-generated (VG) hand movements with the test hand, keeping the control hand stationary. **Measurements:** SpO2 and pulse rate readings from the motion (test) and stationary (control) hands were recorded as well as the number of times and the duration that the oximeters connected to the test hands did not report a reading. Sensitivity, specificity, performance index for SpO2, and pulse rate (PR) were calculated for each pulse oximeter by comparing performance of the test hand with the control hand.

Main Results

During both MG and VG motion, the Masimo Radical had higher SpO2 specificity (93% and 97%) than the Nellcor N-600 (67% and 77%) or the Datex-Ohmeda TruSat (83% and 82%). The Masimo Radical also had higher SpO2 sensitivity (100% and 95%) than the Nellcor N-600 (65% and 50%) or the Datex-Ohmeda TruSat (20% and 15%) during both MG and VG motion. During MG motion, the Masimo Radical had the lowest PR failure rate (0%) compared with the Nellcor N-600 (22.2%) and Datex-Ohmeda TruSat (1.3%). However, during VG motion, the Masimo Radical had the lowest SpO2 failure rate (0%) of the 3 devices (Nellcor N-600 16.4% and Datex-Ohmeda TruSat 1.7%). Both the Masimo Radical and the Datex-Ohmeda TruSat had lower PR failure rates (0% and 4.4%) than the Nellcor N-600 (33.9%). There were no significant differences in SpO2 or PR performance index between the 3 devices.

Machine Generated Motion	Missed Events	Sensitivity (%)	False Alarms	Specificity (%)
Masimo Radical	0/2	100	4/60	93
Nellcor N-600	7/20	65*	20/60	67*
Datex-Ohmeda TruSat	16/20	20*	10/60	83*

Volunteer Generated Motion	Missed Events	Sensitivity (%)	False Alarms	Specificity (%)
Masimo Radical	1/20	95	2/60	97
Nellcor N-600	10/20	50*	14/60	77*
Datex-Ohmeda TruSat	17/20	15*	11/60	82*

* p= <0.05 vs Masimo Radical

Conclusion

The Masimo Radical had higher SpO2 sensitivity and specificity than the Nellcor N-600 and Datex-Ohmeda TruSat during conditions of motion and induced low perfusion in this volunteer study.

04 Prevention of Retinopathy of Prematurity in Preterm Infants through Changes in Clinical Practice and SpO_2 Technology

Castillo A., Deulofeut R., Critz A., Sola A. *Acta Paediatr*. 2011;100(2):188-92.

Aim

To identify whether pulse oximetry technology is associated with decreased retinopathy of prematurity (ROP) and laser treatment.

Methods

Inborn infants <1250 g who had eye exams were compared at 2 centres in 3 periods. In Period 1, the SpO_2 target was ≥93% and pulse oximetry technology was the same in both centres. In Period 2, guidelines for SpO_2 88-93% were implemented at both centres, and Centre B changed to oximeters with signal extraction technology (SET®) while Centre A did not, but did so in Period 3. One ophthalmology department performed eye exams using international criteria.

Results

In 571 newborns <1250 g, birth weight and gestational age were similar in the different periods and centres. At Centre A, severe ROP and need for laser remained the same in Periods 1 and 2, decreasing in Period 3 (6% and 3% respectively). At Centre B, severe ROP decreased from 12% (Period 1) to 5% (Period 2) and need for laser decreased from 5% to 3%, remaining low in Period 3.

Centre	Severe Retinopathy of Prematurity (ROP) Rate		
	Period 1 Pre-policy Change	Period 2 Post-policy Change	Period 3 Post-policy Change
A	13% with Nellcor	13% with Nellcor	6% with Masimo
B	12% with Nellcor	5% with Masimo	4% with Masimo

Figure 1: Incidence of ROP III-IV and Laser Treatment when using Nellcor N-395/N300 or Masimo SET Pulse Oximetry

Conclusion

In a large group of inborn infants <1250 g, a change in clinical practice in combination with pulse oximetry with Masimo SET,® but not without it, led to significant reduction in severe ROP and need for laser therapy. Pulse oximetry selection is important in managing critically ill infants.

01: Pulse Oximetry – Oxygenation (SpO_2), Pulse Rate (PR)

05 Can Changes in Clinical Practice Decrease the Incidence of Severe Retinopathy of Prematurity in Very Low Birth Weight Infants?

Chow L.C., Wright K.W., Sola A.; CSMC Oxygen Administration Study Group. *Pediatrics*. 2003;111(2):339-45.

Objective

A wide variability in the incidence of severe retinopathy of prematurity (ROP) is reported by different centers. The altered regulation of vascular endothelial growth factor from repeated episodes of hyperoxia and hypoxia is an important factor in the pathogenesis of ROP. Strict management of O_2 delivery and monitoring to minimize these episodes may be associated with decreased rates of ROP. The objective of this study was to compare the incidence of and need for surgery for severe ROP (stages > or =3) in infants of 500 to 1500 g birth weight before and after the implementation of a new clinical practice of O_2 management in a large, level 3 neonatal intensive care unit (NICU).

Methods

An oxygen management policy that included strict guidelines in the practices of increasing and weaning a fraction of inspired oxygen (FIO_2) and the monitoring of O_2 saturation parameters in the delivery room during in-house transport of infants to the NICU and throughout hospitalization was implemented in April 1998. The main objectives were to monitor oxygenation levels more precisely and to avoid hyperoxia and repeated episodes of hypoxia-hyperoxia in very low birth weight infants. Included in the policy were equipment for monitoring, initiation of monitoring at birth, avoidance of repeated increases and decreases of the FIO_2, minimization of "titration" of FIO_2, modification of previously used alarm limits, and others. After an educational process, each staff member signed an agreement stating understanding of and future compliance with the guidelines. Examinations were performed by experienced ophthalmologists following international classification and American Academy of Pediatrics recommendations. ROP data from January 1997 to December 2002 for infants of 500 to 1500 g were analyzed as usual and also have been reported to Vermont Oxford Network since 1998.

Results

The incidence of ROP 3 to 4 at this center decreased consistently in a 5-year period from 12.5% in 1997 to 2.5% in 2001. The need for ROP laser treatment decreased from 4.5% in 1997 to 0% in the last 3 years.

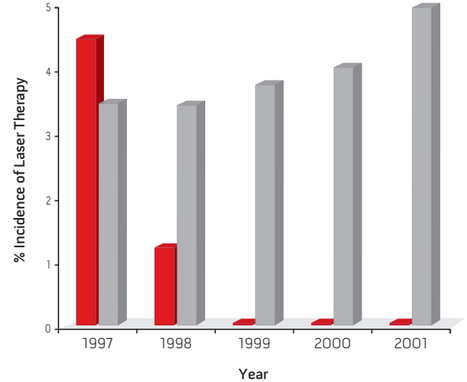


Figure 1: Incidence of ROP laser therapy for infants with birth weight of 500 to 1500 g and born at CSMC (■) and in the VON (□) for 1997 to 2001.

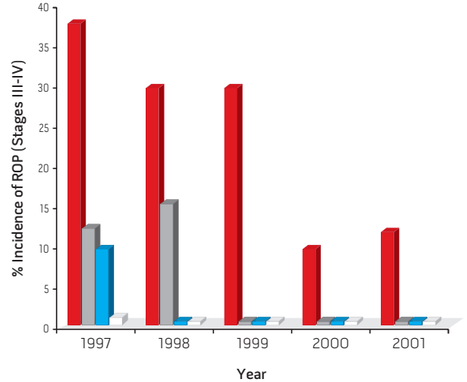


Figure 2: Incidence of ROP stages 3 to 4 (n infants with ROP 3-4/n infants screened) by birth weight-specific groups for infants <1500 g born at CSMC (■ 500-749 g; □ 750-999 g; ■ 1000-1249 g; □ 1250-1500 g).

Conclusion

We observed a significant decrease in the rate of severe ROP in very low birth weight infants in association with an educational program provided to all NICU staff and the implementation and enforcement of clinical practices of O_2 management and monitoring. Although several confounders cannot be excluded, it is likely that differences in these clinical practices may be, at least in part, responsible for the documented inter-center variability in rates of ROP.

06 Impact of Pulse Oximetry Screening on the Detection of Duct- Dependent Congenital Heart Disease: A Swedish Prospective Screening Study in 39,821 Newborns

de-Wahl Granelli A., Wennergren M., Sandberg K., Mellander M., Bejlum C., Inganäs L., Eriksson M., Segerdahl N., Agren A., Ekman-Joelsson B.M., Sunnegårdh J., Verdicchio M., Östman-Smith I. *BMJ*. 2008;337:a3037.

Objective

Prospective screening study with a new generation pulse oximeter before discharge from well-baby nurseries in West Götaland. Cohort study comparing the detection rate of duct-dependent circulation in West Götaland with that in other regions not using pulse oximetry screening. Deaths at home with undetected duct-dependent circulation were included.

Setting

All 5 maternity units in West Götaland and the supraregional referral centre for neonatal cardiac surgery. **Participants**: 39,821 screened babies born between July 1, 2004 and March 31, 2007. Total duct-dependent circulation cohorts: West Götaland n=60, other referring regions n=100. **Main Outcome Measures:** Sensitivity, specificity, positive and negative predictive values, and likelihood ratio for pulse oximetry screening and for neonatal physical examination alone.

Results

In West Götaland, 29 babies in well-baby nurseries had duct-dependent circulation undetected before neonatal discharge examination. In 13 cases, pulse oximetry showed oxygen saturations < or = 90%, and (in accordance with protocol) clinical staff were immediately told of the results. Of the remaining 16 cases, physical examination alone detected 10 (63%). Combining physical examination with pulse oximetry screening had a sensitivity of 24/29 (82.8% [95% CI, 64.2% to 95.2%]) and detected 100% of the babies with duct- dependent lung circulation. Five cases were missed (all with aortic arch obstruction). False positive rate with pulse oximetry was substantially lower than that with physical examination alone (69/39 821 [0.17%] vs 729/38 413 [1.90%], P<0.0001), and 31/69 of the "false positive" cases with pulse oximetry had other pathology. Thus, referral of all cases with positive oximetry results for echocardiography resulted in only 2.3 echocardiograms with normal cardiac findings for every true positive case of duct-dependent circulation. In the cohort study, the risk of leaving the hospital with undiagnosed duct-dependent circulation was 28/100 (28%) in other referring regions versus 5/60 (8%) in West Götaland (P=0.0025, relative risk 3.36 [95% CI, 1.37 to 8.24]). In the other referring regions, 11/25 (44%) of babies with transposition of the great arteries left the hospital undiagnosed versus 0/18 in West Götaland (P=0.0010), and severe acidosis at diagnosis was more common (33/100 [33%] vs 7/60 [12%], P=0.0025, relative risk 2.8 [1.3 to 6.0]). Excluding premature babies and Norwood surgery, babies discharged without diagnosis had higher mortality than those diagnosed in hospital (4/27 [18%] vs 1/110 [0.9%], P=0.0054). No baby died from undiagnosed duct-dependent circulation in West Götaland versus 5 babies from the other referring regions.

The following chart shows the performance of screening methods in the detection of duct-dependent circulation in newborn infants in West Götaland (July 1, 2004 to March 31, 2007).

	Physical Examination Alone (n=38,374)	Pulse Oximetry (n=38,429)	Physical Examination Plus Pulse Oximetry (n=38,429)
Sensitivity (95% CI) (%)	62.50 (35.43 to 84.80)	62.07 (42.3 to 79.31)	82.76 (64.23 to 94.15)
Specificity (95% CI) (%)	98.07 (97.93 to 98.21)	99.82 (99.77 to 99.86)	97.88 (97.73 to 98.03)
Positive Predictive Value (95% CI) (%)	1.35 (0.65 to 2.47)	20.69 (12.75 to 30.71)	2.92 (1.88 to 4.31)
Negative Predictive Value (95% CI) (%)	99.98 (99.96 to 99.99)	99.97 (99.95 to 99.99)	99.99 (99.97 to 100.00)
False-positive Rate (%)	1.90	0.17	2.09

Conclusion

Introducing pulse oximetry screening before discharge improved total detection rate of duct-dependent circulation to 92%. Such screening seems cost neutral in the short term, but the probable prevention of neurological morbidity and reduced need for preoperative neonatal intensive care suggest that such screening will be cost effective in the long term.

01: Pulse Oximetry – Oxygenation (SpO_2), Pulse Rate (PR)

07 Screening for Duct-Dependent Congenital Heart Disease with Pulse Oximetry: A Critical Evaluation of Strategies to Maximize Sensitivity

de-Wahl Granelli A., Mellander M., Sunnegårdh J., Sandberg K., Ostman-Smith I. *Acta Paediatr*. 2005;94(11):1590-159.

Aim

To evaluate the feasibility of detecting duct-dependent congenital heart disease before hospital discharge by using pulse oximetry.

Methods

Design: Case-control study. **Setting:** A supra regional referral centre for paediatric cardiac surgery in Sweden. **Patients:** 200 normal-term newborns with echocardiographically normal hearts (median age 1.0 d) and 66 infants with critical congenital heart disease (CCHD; median age 3 d). **Methods:** Pulse oximetry was performed in the right hand and 1 foot using a new-generation pulse oximeter (NGoxi) and a conventional-technology oximeter (CToxi).

Results

With the NGoxi, normal newborns showed a median postductal saturation of 99% (range 94-100%); intra observer variability showed a mean difference of 0% (SD 1.3%), and inter observer variability was 0% (SD 1.5%). The CToxi recorded a significantly greater proportion of postductal values below 95% (41% vs 1%) in the normal newborns compared with NGoxi (p<0.0001). The CCHD group showed a median postductal saturation of 90% (45-99%) with the NGoxi. Analysis of distributions suggested a screening cut-off of <95%; however, this still gave 7/66 false-negative patients, all with aortic arch obstruction. Best sensitivity was obtained by adding one further criterion: saturation of <95% in both hand and foot or a difference of >±3% between hand and foot. These combined criteria gave a sensitivity of 98.5%, specificity of 96.0%, positive predictive value of 89.0%, and negative predictive value of 99.5%.

Screening Performance for Critical Congenital Heart Disease at Different Cut-off Criteria Using Our Observations

Criterion for Positive Test	Sensitivity (%)	Specificity (%)	PPV (%)	NPV (%)
< 92% in foot or 7% lower in foot	66.7	100	100	90.1
< 95% in both right hand and foot	77.3	100	100	93.0
< 95% in right hand	83.3	98.0	93.2	95.1
< 95% in foot	89.4	99.0	96.7	96.6
< 95% in both right hand and foot or foot saturation > 3% lower than right hand	92.4	99.5	98.4	97.5
< 95% in both right hand and foot or foot saturation > 3% lower or higher than right hand	98.5	96.0	88.9	99.5

PPV: positive predictive value; NPV: negative predictive value

Conclusion

Systematic screening for CCHD with high accuracy requires a new-generation oximeter, and comparison of saturation values from the right hand and one foot substantially improves the detection of CCHD.

08 More Reliable Oximetry Reduces the Frequency of Arterial Blood Gas Analyses and Hastens Oxygen Weaning After Cardiac Surgery: A Prospective, Randomized Trial of the Clinical Impact of a New Technology

Durbin C.G. Jr., Rostow S.K. *Crit Care Med*. 2002;30(8):1735-40.

Introduction

Objective: Evaluation of the impact on clinical care of improved, innovative oximetry technology. **Design:** Randomized, prospective trial. **Setting:** Post cardiac surgery intensive care unit in a major teaching hospital.

Methods

Patients: A total of 86 patients after undergoing coronary artery bypass surgery. **Interventions:** All patients were monitored with 2 oximeters: 1 employing conventional oximetry (conventional pulse oximeter, CPO) and 1 using an improved innovative technology (innovative pulse oximeter, IPO), on different fingers of the same hand. The outputs from both devices were collected continuously by computer, but only 1 device was randomly selected and displayed for clinicians.

Results

The amount and percentage of nonfunctional monitoring time was collected and found to be much greater for the CPO than the IPO (8.7% ± 16.4% for CPO vs 1.2% ± 3.3% for IPO, p =0.000256). Time to extubation was not different between the 2 groups (634 ± 328 min for IPO vs 706 ± 459 min for CPO). Clinicians managing patients with the more reliable IPO weaned patients faster to an FiO_2 of 0.40 (176 ± 111 min for IPO vs 348 ± 425 min for CPO, p =0.0125), obtained fewer arterial blood gas measurements (2.7 ± 1.2 for IPO vs 4.1 ± 1.6 for CPO, p =0.000015), and made the same number of ventilator changes during this weaning process (2.9 ± 1.2 for IPO vs 2.9 ± 1.7 for CPO).

Oximeter Used	Age, Yrs	Average Time to Extubation, Min ± SD	No of ABGs to Extubation or FiO_2 = 0.4 ± SD	Average Time to FiO_2 = 0.4, Min ± SD	No of Ventilator Changes to FiO_2 = 0.4 ± SD
Masimo SET®	63 ± 12.9	634 ± 329	2.7 ± 1.2	176 ± 111	2.9 ± 1.2
Ohmeda 3740	64 ± 8.6	706 ± 459	4.1 ± 1.6	348 ± 425	2.9 ± 1.7
Significance, p	0.827	0.412	0.000015	0.0125	0.908

Conclusion

Provision of more reliable oximetry allows caregivers to act in a more efficient and cost-effective manner in regard to oxygen weaning and use of arterial blood gas measurements. Investigating the effect of a monitor on the process of care, rather than simply its accuracy and precision, is a useful, relevant paradigm for evaluating the value and impact of a new technology.

09 Reliability of Conventional and New Pulse Oximetry in Neonatal Patients

Hay W.W., Rodden D.J., Collins S.M., Melara D.L., Hale K.A., Fashaw L.M. *J Perinatol*. 2002;22(5):360-6.

Introduction

Pulse oximetry is widely used in the NICU, but clinicians often distrust the displayed values during patient motion, ie, questionable oxygen saturation (SpO_2) and pulse rate (PR) values. Masimo Corporation (Irvine, CA) has developed pulse oximetry with claims of resistance to sources of interference. To test this premise, we compared the performance of the Masimo SET pulse oximeter to a conventional device (Nellcor N-200) and then with 3 other new-generation pulse oximeters (Nellcor N-395, Novametrix MARS, and Philips Viridia 24C).

Methods

We studied 26 nonsedated NICU infants who were on supplemental oxygen and/or mechanical ventilation. ECG heart rate (HR) from a bedside monitor and SpO_2 and PR from the 2 pulse oximeters were captured by a PC for a total of 156 hours. The ECG HR and pulse oximeter spectral waveform were analyzed at alarms for hypoxemia (SpO_2 < or = 85%) and/or bradycardia (HR < or = 80 bpm). We then compared the performance of the Masimo SET to 3 other new-generation pulse oximeters, Nellcor N-395, Novametrix MARS, and Philips Viridia 24C, in a similar population of 7 infants for a total of 28 hours. We added to the test criteria the ability of the various pulse oximeters to track acute changes in HR.

Results

Compared with Nellcor, Masimo SET had 86% fewer false alarms, which also were shorter in duration, resulting in 92% less total alarm time. Masimo SET also identified nearly all bradycardias versus 14% for the Nellcor. Compared with the new-generation pulse oximeters, false desaturations, data drop-outs, and false bradycardias were lowest for Masimo SET, as was the capture of true desaturations and bradycardias. Notably, the new-generation devices differed greatly in their ability to detect changes in HR (ie, the frequency of frozen PR during times of ECG HR change was 0, 6, 11, and 46 for Masimo, Nellcor, Philips, and Novametrix, respectively).

	Masimo SET®	Nellcor N-395	Novametrix MARS	Philips Viridia 24C
"False" Hypoxemia	1	42	33	10
Missed Desaturations	1	4	12	6
"False" Bradycardia	1	1	61	2
Frozen Pulse Rate	0	6	46	11
Data Drop-out	1	10	93	21

Conclusion

Masimo SET pulse oximetry recorded markedly fewer false SpO_2 and PR alarms and identified more true hypoxic and bradycardic events than either conventional or other new-generation pulse oximeters. Masimo SET also most closely reflected the ECG rate irrespective of accelerations or decelerations in HR.

Masimo-supported Study

10 "Motion-Resistant" Pulse Oximetry: A Comparison of New and Old Models

Barker S.J. *Anesth Analg*. 2002;95(4):967-72.

Introduction

Several pulse oximeter manufacturers have recently developed instruments that are claimed to be resistant to the effects of patient motion. We performed a laboratory volunteer experiment to compare the performances of several of these instruments, as well as some older models, during combinations of motion and hypoxemia.

Methods

Twenty oximeters were studied. A motorized table produced different hand motions, and each motion was studied during both room air breathing and hypoxemia. Pulse oximeters on the nonmoving hand were used to provide control measurements for comparison.

Results

The Masimo SET pulse oximeter exhibited the best overall performance, with a performance index (percentage of time in which the SpO_2 reading is within 7% of control value) of 94%. The Philips Viridia 24C was next, with an 84% index, followed by the Philips CMS (80%), the Datex-Ohmeda 3740 (80%), and the Nellcor N-395 (69%). For comparison with older oximeter technology, the Criticare 5040 had an index of 28%.

Pulse Oximeter	SpO_2 Performance Index	Pulse Rate Performance Index	SpO_2 Sensitivity	SpO_2 Specificity	Dropout Rate (%)	Bias (%)	Precision (%)
Masimo SET®	94	85	98	93	0.2	-0.41	2.98
Philips Viridia 24C (Rev B.O.)*	84	75	78	90	1.6	-1.52	4.51
Philips CMS (Rev B.O.)*	80	73	70	83	3.7	-1.87	5.96
Datex-Ohmeda 3740	80	11	68	80	0.0	-2.33	4.20
Datex-Ohmeda 3800	79	12	63	77	0.7	-2.24	4.17
Datex-Ohmeda AS/3	77	67	90	45	0.2	-3.73	5.30
Nellcor N-395 (v 1620)*	71	47	66	78	4.1	-3.17	5.44
Datex-Ohmeda 3900	68	12	60	52	1.0	-3.20	4.22
Novametrix MARS (2000-10)*	58	27	40	42	2.4	-4.42	5.39
Hewlett-Packard CMS	57	20	63	30	0.5	-8.52	7.11
Nellcor N-180	57	15	35	43	3.1	-5.90	5.95
Marquette 8000	55	27	40	45	0.2	-6.22	6.68
Nellcor NPB-295	55	16	39	53	8.0	-5.79	6.21
Novametrix 520A	54	11	35	30	0.7	-5.03	5.07
Nellcor N-200	53	19	53	43	0.8	-7.18	5.97
BCI 3304	53	10	28	25	1.2	-7.38	5.74
Nonin 8600	48	13	45	18	1.4	-6.19	5.67
SpaceLabs 90308	46	40	40	23	0.8	-9.50	6.89
Nellcor NPB-190	43	16	48	33	11.1	-9.41	6.07
Criticare 5040	27	5	30	15	5.4	-12.64	6.44

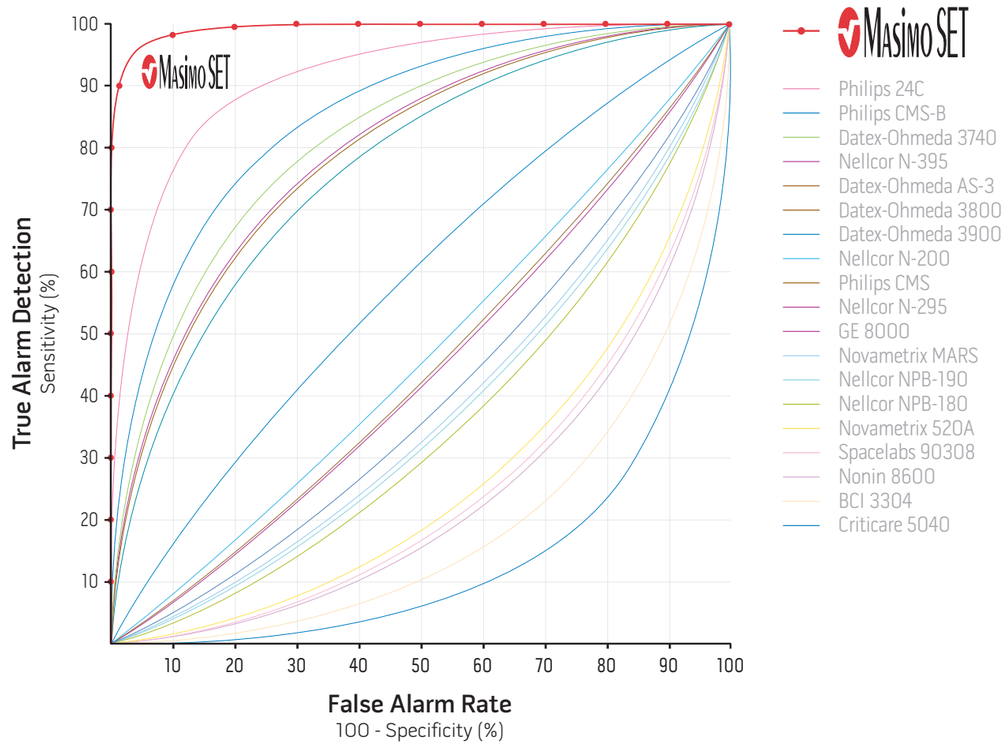
* indicates pulse oximeters which claim "motion resistance"

Table 1: Pulse oximeters are listed in descending order of SpO_2 performance index, which is the percentage of time the pulse oximeter displays an SpO_2 within 7% of control.

01: Pulse Oximetry – Oxygenation (SpO_2), Pulse Rate (PR)

Figure 1: Receiver operating characteristic (ROC) curves calculated for 20 pulse oximeters in this study. The best-performance ROC curves lie in the upper left corner. Diagnosis of hypoxemia by a coin toss would produce an ROC curve along the line of identity, x=y.

Results



Conclusion

Recent technology changes have significantly improved pulse oximeter performance during motion artifact, with the Masimo oximeter leading the way. **Implications:** New improvements in pulse oximeter technology have resulted in significantly better accuracy and reliability during patient motion. The Masimo pulse oximeter demonstrated the best performance of the 20 instruments tested.

11 Usefulness of Pulse Oximetry Using the SET Technology in Critically Ill Adult Patients

Levrat Q., Petitpas F., Bouche G., Debaene B., Mimoz O. *Ann Fr Anesth Reanim*. 2009;28(7-8):640-4.

Background

Pulse oximeters are routinely used in severely ill patients to detect hypoxemia early. In various clinical situations, however, conventional devices may be unable to display valid values or any value whatsoever. The usefulness of the Signal Extraction Technology (SET) in these situations has not yet been investigated.

Methods

Twenty-five adult patients requiring norepinephrine, regardless of the reason or dosage, or having a defective signal with a conventional oximeter were equipped with both their conventional saturation sensor (Oxymax Nellcor) and a SET saturation sensor (Masimo) connected to its monitor. Saturation values displayed by each pulse oximeter and the SaO_2 measured concomitantly by CO-Oximetry were gathered on inclusion and then whenever 1 of the 2 sensors did not display a value, or when the difference between the values was greater than 5 saturation points, or at any time a blood gas analysis was done.

Results

During the study period, 83 measures were collected. Using the Bland-Altman method, SaO_2 estimates by the SET system were more accurate than those by the conventional system (bias ± 2 SD of 0.0% ± 3.1% vs 2.1% ± 11.0%, respectively), even when only valid values (values accompanied by a satisfactory quality index) were considered (0.0% ± 2.7% vs 1.2% ± 7.0%).

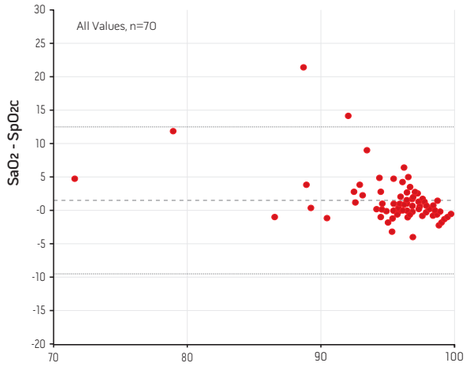


Figure 1: Bland-Altman Plot showing bias and limits of agreement of Nellcor Oxymax compared to SaO_2 values.

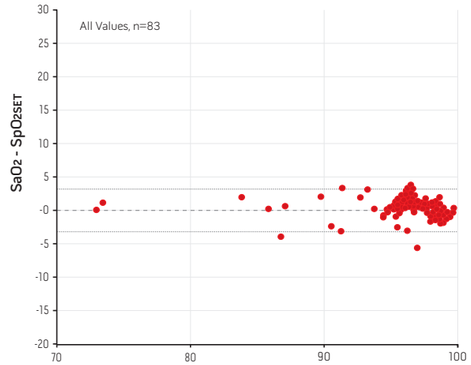


Figure 2: Bland-Altman Plot showing bias and limits of agreement of Masimo SET compared to SaO_2 values.

Conclusion

In situations at risk of producing defective signals when using conventional sensors, the SET system provided more valid SaO_2 estimates.

12 Pulse Oximetry Screening for Congenital Heart Defects in Newborn Infants (Pulseox): A Test Accuracy Study

Ewer A.K., Middleton L.J., Furmston A.T., Bhoyar A., Daniels J.P., Thangaratinam S., Deeks J.J., Khan K.S. *Lancet*. 2011;378(9793):785-94.

Background

Screening for congenital heart defects relies on antenatal ultrasonography and postnatal clinical examination; however, life-threatening defects often are not detected. We prospectively assessed the accuracy of pulse oximetry as a screening test for congenital heart defects.

Methods

In 6 maternity units in the UK, asymptomatic newborn babies (gestation >34 weeks) were screened with pulse oximetry before discharge. Infants who did not achieve predetermined oxygen saturation thresholds underwent echocardiography. All other infants were followed up to 12 months of age by use of regional and national registries and clinical follow-up. The main outcome was the sensitivity and specificity of pulse oximetry for detection of critical congenital heart defects (causing death or requiring invasive intervention before 28 days) or major congenital heart disease (causing death or requiring invasive intervention within 12 months of age).

Findings

Of the 20,055 newborn babies who were screened, 53 had major congenital heart disease (24 critical), a prevalence of 2.6 per 1000 live births. Analyses were done on all babies for whom a pulse oximetry reading was obtained. Sensitivity of pulse oximetry was 75.00% (95% CI, 53.29–90.23) for critical cases and 49.06% (35.06–63.16) for all major congenital heart defects. In 35 cases, congenital heart defects were already suspected after antenatal ultrasonography, and exclusion of these reduced the sensitivity to 58.33% (27.67–84.83) for critical cases and 28.57% (14.64–46.30) for all cases of major congenital heart defects. False-positive results were noted for 169 (0.8%) babies (specificity 99.16%, 99.02–99.28), of which 6 cases were significant, but not major, congenital heart defects and 40 were other illnesses that required urgent medical intervention.

Accuracy of Pulse Oximetry in Full Cohort (n = 20,055)

	Critical Cases Alone	All Major Cases
True Positives	18	26
False Negatives	6	27
False Positives	177	169
True Negatives	19,854	19,833
Sensitivity	75.00% (53.29-90.23)	49.06% (35.06-63.16)
Specificity	99.12% (98.98-99.24)	99.16% (99.02-99.28)
Positive Predictive Value	9.23% (5.56-14.20)	13.33% (8.90-18.92)
Negative Predictive Value	99.97 (99.93-99.99)	99.86% (99.80-99.91)

Data are number or percentage (95% CIs).

Interpretation

Pulse oximetry is a safe, feasible test that adds value to existing screening. It identifies cases of critical congenital heart defects that go undetected with antenatal ultrasonography. The early detection of other diseases is an additional advantage.

13 False Alarms and Sensitivity of Conventional Pulse Oximetry versus the Masimo SET Technology in the Pediatric Postanesthesia Care Unit

Malviya S., Reynolds P.I., Voepel-Lewis T., Siewert M., Watson D., Tait A.R., Tremper K. *Anesth Analg*. 2000;90(6):1336-40.

Introduction

We compared the incidence and duration of false alarms (FA) and the sensitivity of conventional pulse oximetry (CPO) with Masimo Signal Extraction Technology (Masimo SET; Masimo Corporation, Irvine, CA) in children in the postanesthesia care unit.

Methods

Disposable oximeter sensors were placed on separate digits of one extremity. Computerized acquisition of synchronous data included electrocardiograph heart rate, SpO_2, and pulse rate via CPO and Masimo SET. Patient motion, respiratory, and other events were simultaneously documented. SpO_2 tracings conflicting with clinical observations and/or documented events were considered false. These were defined as 1) Data dropout, complete interruption in SpO_2 data; 2) False negative, failure to detect SpO_2 </= 90% detected by another device or based on observation/intervention; 3) FA, SpO_2 </= 90% considered artifactual; and 4) True alarm (TA), SpO_2 </= 90% considered valid. Seventy-five children were monitored for 35 ± 22 min/patient (42 h total).

Results

There were 27 TAs, all of which were identified by Masimo SET and only 16 (59%) were identified by CPO ($p<0.05$). There was twice the number of FAs with CPO (10 vs 4 Masimo SET; $p<0.05$). The incidence and duration of data dropouts were similar between Masimo SET and CPO. Masimo SET reduced the incidence and duration of FAs and identified a more frequent incidence of TAs compared with CPO.

	Masimo SET®		Nellcor N-200	
	Events	Duration (sec)	Events	Duration (sec)
True Alarms Missed	0	0	11	99
False Alarms	4	319	10	676
True Alarms Detected	27	2364	16	1468

Implications

Pulse oximetry that incorporates Masimo Signal Extraction Technology (Masimo Corporation, Irvine, CA) may offer an advantage over conventional pulse oximetry by reducing the incidence of false alarms while identifying a higher number of true alarms in children in the postanesthesia care unit.

14 Avoiding Hyperoxemia During Neonatal Resuscitation: Time to Response of Different SpO_2 Monitors

Baquero H., Alviz R., Castillo A., Neira F., Sola A. *Acta Paediatr*. 2011;100(4):515-8.

Aim

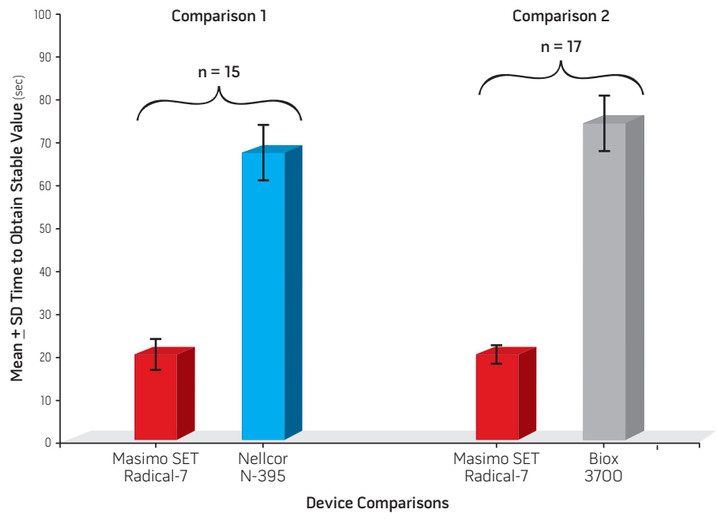
To assess the time to obtain reliable oxygen saturation readings by different pulse oximeters during neonatal resuscitation in the delivery room or NICU.

Methods

Prospective study comparing 3 different pulse oximeters: Masimo Radical-7 compared simultaneously with Ohmeda Biox 3700 or Nellcor N-395 in newborn infants who required resuscitation. Members of the research team placed the sensors for each of the pulse oximeters being compared simultaneously, one sensor on each foot of the same baby. Care provided routinely, without interference by the research team. The time elapsed until a reliable SpO_2 was obtained was recorded using a digital chronometer. Statistical comparisons included chi-square and Student's t-test.

Results

Thirty-two infants were enrolled; median gestational age was 32 weeks. Seventeen paired measurements were made with the Radical-7 and Biox 3700; mean time to a stable reading was 20.2±7 sec for the Radical-7 and 74.2±12 sec for the Biox 3700 ($p=0.02$). The Radical-7 and the N-395 were paired on 15 infants; the times to obtain a stable reading were 20.9±4 sec and 67.3±12 sec, respectively ($p=0.03$).



Conclusion

The time to a reliable reading obtained simultaneously in neonatal critical situations differs by the type of the pulse oximeter used, being significantly faster with Masimo Signal Extraction Technology. This may permit for better adjustments of inspired oxygen, aiding in the prevention of damage caused by unnecessary exposure to high or low oxygen.

15 Accuracy of Pulse Oximeters Intended for Hypoxemic Pediatric Patients

Harris BU, Char DS, Feinstein JA, Verma A, Shiboski SC, Ramamoorthy C. *Pediatr Crit Care Med*. 2016 Apr;17(4):315-20.

Objectives

Prior studies have shown inaccuracies in pulse oximetry readings at saturations less than 85%; however, no large studies have evaluated new sensors marketed for these low saturations. This study's purpose was to evaluate two sensors with claims of improved accuracy in children with saturations less than 85%.

Design

Prospective observational study.

Setting

Single institution; cardiac catheterization laboratory, and operating room.

Patients

Fifty patients weighing 3-20 kg with baseline saturations less than 90% undergoing surgical or catheterization procedure.

Measurements and Main Results

Data collected included demographics, diagnosis, continuous saturations from three different pulse oximeters (Masimo LNCS [Masimo, Irvine, CA], Masimo Blue [Masimo], and Nellcor Max-I [Medtronic, Dublin, Ireland]) and up to four blood samples for CO-Oximetry as the gold-standard arterial oxygen saturation. Analysis included scatter plots, smoothed regression estimates of mean continuous saturation levels plotted against corresponding arterial oxygen saturation values, and Bland-Altman plots. Bland-Altman analysis indicated increasing levels of bias and variability for decreasing arterial oxygen saturation levels for all three sensors, with a statistically significant increase in mean difference observed for decreasing arterial oxygen saturation level. The Masimo Blue sensor had the lowest mean difference, SD and Bland-Altman limits in patients with saturations less than or equal to 85%. At saturation range of less than or equal to 85% and greater than 75%, 14% of the samples obtained from Masimo Blue, 24% of the readings from the Nellcor, and 31% from the Masimo Standard sensors were greater than or equal to 5% points difference. All three sensors had a further increase in these differences for arterial oxygen saturation values less than 75%.

Conclusion

The Masimo Blue sensor has improved accuracy at saturations 75-85% versus the Nellcor and Masimo Standard sensors. The accuracy of peripheral capillary oxygen saturation of the Masimo Blue sensor was within 5% points of the arterial oxygen saturation the majority of the time. Currently, at saturations less than or equal to 85%, pulse oximetry alone should not be relied on in making clinical decisions.

Method	All SaO_2 Values % (*n*)	SaO_2 ≤ 75% % (*n*)	75% < SaO_2 ≤ 85% % (*n*)	SaO_2 ≥ 85% % (*n*)
Masimo Blue	17 (185)	29 (35)	14 (95)	16 (55)
Nellcor	25 (182)	51 (35)	24 (91)	11 (56)
Masimo Standard	29 (183)	36 (33)	31 (94)	21 (55)

SaO_2 = arterial blood oxygen saturation, *n* = no. of paired measurements.

Table 1: Sensor measurements greater than or equal to 5% different than corresponding arterial blood oxygen saturation values.

01: Pulse Oximetry – Oxygenation (SpO_2), Pulse Rate (PR)

16 Longevity of Masimo and Nellcor Pulse Oximeter Sensors in the Care of Infants

Erler T., Avenarius S., Wischniewski E., Schmidt K., Kläber H.G. *J Perinatol*. 2003;23(2):133-5.

Objective

Pulse oximetry is a standard of care for monitoring oxygenation in neonates. Associated with the use of pulse oximetry is the cost of patient sensors, especially if the sensor is designed for single-patient use. Pulse oximetry monitoring of sick newborns is routine, often lengthy and, if the pulse oximeter sensor is short-lived, can result in a significant portion in the cost of intensive care.

Methods

We evaluated, in the NICUs of 2 hospitals and a step-down nursery, the useful life of disposable neonatal pulse oximeter sensors from 2 manufacturers: Masimo and Nellcor. The only requisites were ethics committee approval and need for monitoring. The timed of PO sensor placement and replacement were noted along with the reason for changing the sensor.
The standard care practices for PO and sensor use in the respective institutions were followed.

Results

A total of 835.5 patient days of monitoring were accumulated with 65 infants in the Masimo group and 56 using Nellcor. The Masimo Neo sensors had over twice (2.33) the useful life of the Nellcor N-25 (9.05 $\pm$ 4.4 vs. 3.9 $\pm$ 2.3 days (range of 7.2-11.8 and 2.5-5.8 days, respectively, $p<0.05$)). The magnitude of useful life between the 2 institutions was not significantly different in the Masimo group (2.35- vs. 2.22-fold). PO sensors were replaced due to impaired adhesion (38 Masimo and 32 Nellcor) and no signal (6 Masimo and 4 Nellcor).

Longevity of Nellcor and Masimo Pulse Oximeter Sensors in Cottbus and Magdeburg

	Longevity Nellcor Oxisensor II N-25		Longevity Masimo SET® LNOP NeoPT and LNOP	
	Median (days) and SD	Interquartile Range	Median (days) and SD	Interquartile Range
Cottbus	3.7 $\pm$ 2.2	0.6; 7.2	8.2 $\pm$ 3.62	3.4; 20.4
Magdeburg	4.9 $\pm$ 2.3	1.8; 8.2	11.5 $\pm$ 4.5	4.6; 17.8
All	**3.9** $\pm$ 2.3	2.5; 5.8	**9.05** $\pm$ 4.4	7.2; 11.8

Bold implies $p<0.05$ is significant.

Conclusion

We found a more than two-fold increase in the life of Masimo versus Nellcor sensors. This difference was consistent between various caregivers in multiple settings and corroborates the experience of another, more limited study. A cost savings should result from the use of Masimo versus Nellcor disposable pulse oximeter sensors in neonatal routine care.

17 Differences in Pulse Oximetry Technology Can Affect Detection of Sleep-Disordered Breathing in Children

Brouillette R.T., Lavergne J., Leimanis A., Nixon G.M., Ladan S., McGregor C.D. *Anesth Analg*. 2002;94(1 Suppl):S47-53.

Introduction

Newer pulse oximeters have been developed to be motion resistant and thus have few false alarms. However, they have not yet been evaluated in a pediatric sleep laboratory setting. While evaluating new oximeters for use in our laboratory, we obtained simultaneous pulse oximetry data from 2 Masimo oximeters and from 2 Nellcor oximeters during nocturnal polysomnography in children referred for sleep-disordered breathing (SDB).

Methods and Results

In series 1, comprising 24 patients, comparisons were made between a Masimo oximeter with 4-second averaging time and the Nellcor N-200 oximeter set for 3 to 5 second averaging. A maximum of 20 events per patient were randomly selected for analysis, an "event" being a desaturation of > or = 4% registered by either oximeter. Interobserver agreement for event classification was 93%. Eighty-eight percent of 220 desaturation events occurring during wakefulness and 38% of 194 events occurring during sleep were classified as motion artifact on the Nellcor oximeter. Neither the Masimo oximeter nor the transcutaneous oxygen probe confirmed that the desaturation was real, in most of these cases. During sleep, there were 119 events detected by either or both oximeters: 113 (95%) by the Nellcor versus 82 (69%) by the Masimo. For these 119 events, the extent of desaturation was slightly less for the Masimo than the Nellcor oximeter, 4.5 ± 2.4% vs 5.5 ± 2.5%, respectively.

In series 2, 22 patients were studied comparing a Masimo Radical oximeter with 2 second averaging to the Nellcor N-200 oximeter. The extent of desaturation was slightly greater for the Masimo oximeter. The Masimo oximeter detected more non-artifactual desaturation events occurring during sleep than the Nellcor oximeter, 90% vs 76% (chi2 = 9.9, p < 0.01).

In series 3, comprising 128 events in 5 patients, a Nellcor N-395 oximeter detected fewer desaturations during non-movement, sleep periods and had more movement-related "desaturation" events compared to a Masimo Radical oximeter.

This figure shows a typical type M event, one in which motion caused a false desaturation event on the Nellcor oximeter.

Conclusion

The Masimo oximeters register many fewer false desaturations due to motion artifact. Using 4-second averaging, a Masimo oximeter detected significantly fewer SaO_2 dips than the Nellcor N-200 oximeter, but using 2-second averaging, the Masimo oximeter detected more SaO_2 dips than the Nellcor N-200 oximeter. The sensitivity and motion artifact rejection characteristics of the Nellcor N-395 oximeter are not adequate for a pediatric sleep laboratory setting. These findings suggest that in a pediatric sleep laboratory, use of a Masimo oximeter with very short averaging time could significantly reduce workload and improve reliability of desaturation detection.

18 Noninvasive Peripheral Perfusion Index as a Possible Tool for Screening for Critical Left Heart Obstruction

Granelli A.W., Ostman-Smith I. *Acta Paediatr*. 2007;96(10):1455-9.

Aim

Peripheral perfusion index (PPi) has been suggested as a possible method to detect illness causing circulatory embarrassment. We aimed to establish the normal range of this index in healthy newborns and compare it with newborns with duct-dependent systemic circulation.

Methods

Design: We conducted a case-control study. **Setting:** Our study population comprised 10,000 prospectively recruited newborns from Västra Götaland, Sweden. **Patients:** A total of 10,000 normal newborns and 9 infants with duct-dependent systemic circulation (left heart obstructive disease [LHOD] group) participated in the study. **Interventions:** We conducted single preductal and postductal measurements of PPi with a new generation pulse oximeter (Masimo Radical SET) before discharge from hospital.

Results

PPi values between 1 and 120 h of age show an asymmetrical, non-normal distribution with median PPI value of 1.70 and interquartile range of 1.18-2.50. The 5th percentile = 0.70 and 95th percentile = 4.50. All infants in the LHOD group had either preductal or postductal PPI below the interquartile range, and 5 of 9 (56%) were below the 5th percentile cut-off of 0.70 ($p < 0.0001$, Fisher's exact test). A PPI value <0.70 gave an odds ratio for LHOD of 23.75 (95% CI, 6.36-88.74).

Perfusion Index Reference Values

	Median Value	Interquartile Range	5th Percentile
Normal Infants (n=10,000)	1.70	1.18-2.50	0.70

Perfusion Index of Right Hand and Foot of 9 Infants with LHOD

Diagnosis	Right Hand	Foot
Interrupted Aortic Arch, Aortopulmonary Window	0.36	1.27
Interrupted Aortic Arch	0.77	0.43
Critical Aortic Stenosis	0.082	1.38
Coarctation of the Aorta	1.00	1.48
Coarctation of the Aorta	2.8	0.17
Coarctation of the Aorta	1.10	0.25
Coarctation of the Aorta	0.37	1.23
Hypoplastic Left Heart Syndrome	0.065	2.15
Hypoplastic Left Heart Syndrome	0.082	1.38

Conclusion

PPi values lower than 0.70 may indicate illness and a value <0.50 (1st percentile) indicates definite under perfusion. PPi values might be a useful additional tool for early detection of LHOD.

19 The Perfusion Index Derived from a Pulse Oximeter for Predicting Low Superior Vena Cava Flow in Very Low Birth Weight Infants

Takahashi S., Kakiuchi S., Nanba Y., Tsukamoto K., Nakamura T., Ito Y. *J Perinatol*. 2010;30(4):265-9.

Objective

Superior vena cava (SVC) flow is used as an index for evaluating systemic blood flow in neonates. Thus far, several reports have shown that low SVC flow is a risk factor for intraventricular hemorrhage (IVH) in the preterm infant. Therefore, it is likely to be a useful index in the management of the preterm infant. The perfusion index (Pi) derived from a pulse oximeter is a marker that allows noninvasive and continuous monitoring of peripheral perfusion. The objective of this paper was to determine the accuracy of the Pi for detecting low SVC flow in very low birth weight infants born before 32 weeks of gestation.

Study Design

We studied the correlation between Pi and SVC flow 0 to 72 h after birth in very low birth weight infants born before 32 weeks of gestation. The best cut-off value for low SVC flow was calculated from the respective receiver-operating characteristic curves.

Results

A positive correlation was found between the Pi and SVC flow (r=0.509, p<0.001). The best cut-off value for the Pi to detect low SVC flow was 0.44 (sensitivity 87.5%, specificity 86.3%, positive predictive value 38.9%, negative predictive value 98.6%).

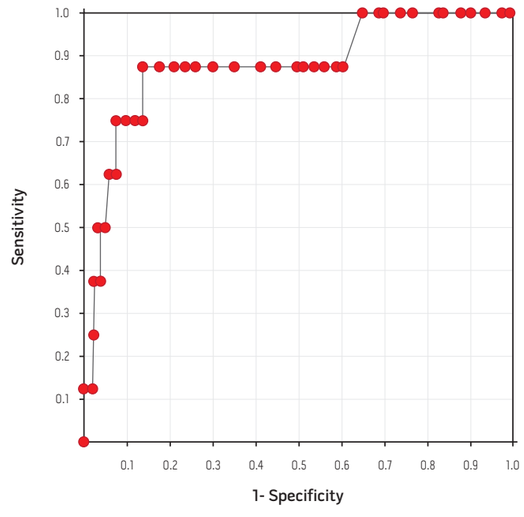


Figure 1: The Receiver-Operating Characteristic (ROC) curves for the PI.

Conclusion

This study found that the Pi was associated with SVC flow, and it was a useful index for detecting low SVC flow in very low birth weight infants born before 32 weeks of gestation. Therefore, use of the Pi should be evaluated in the cardiovascular management of the preterm infant.

20 Maternal Pulse Oximetry Perfusion Index as a Predictor of Early Adverse Respiratory Neonatal Outcome After Elective Cesarean Delivery

De Felice C., Leoni L., Tommasini E., Tonni G., Toti P., Del Vecchio A., Ladisa G., Latini G. *Pediatr Crit Care Med*. 2008;9(2):203-8.

Objective

Evidence suggests increased morbidity, in particular early neonatal respiratory complications, in newborns from elective cesarean section compared with those from vaginal delivery. No reliable maternal predictors of adverse neonatal outcome at elective cesarean section are known. Here, we prospectively tested the hypothesis that a low maternal perfusion index at the baseline phase (ie, pre-anesthesia) of the elective cesarean section is a predictor of early adverse neonatal respiratory outcome.

Methods

Design: Prospective cohort study. **Setting:** Operating and delivery rooms of a public health hospital with a tertiary-level neonatal intensive care unit. **Patients:** Forty-four healthy pregnant women with no known risk factors undergoing elective cesarean section at term gestation. **Interventions:** Elective cesarean section was divided into 9 phases. Analysis of pulse oximetry-derived signals (perfusion index, pulse rate, and oximetry) and systolic, diastolic, and differential blood pressure were recorded. Maternal arterial and venous newborn cord blood gas analyses and placental histology were evaluated.

Results

Early respiratory complications (transient tachypnea of the newborn, n=5; respiratory distress syndrome, n=1) were observed in 13.6% (6 of 44) of the newborns. A maternal perfusion index < or = 1.9 (lower quartile) during the pre-anesthesia phase of the elective cesarean section was an independent predictor of early adverse neonatal respiratory outcome (odds ratio 68.0, 95% confidence interval 6.02-767.72; p<.0001).

Maternal Pulse Oximetry Variations During Elective Cesarean Section as a Function of Early Adverse Neonatal Respiratory Outcome

Variable	Adverse Outcomes (n=6)	No Adverse Outcomes (n=38)	*p* Value
Perfusion Index (%)	2.67 (2.34-3.21)	7.49 (7.08-8.05)	<0.0001
Pulse Rate (bpm)	100 (98-103)	93 (91-95)	<0.0001
SpO_2 (%)	99 (98-99)	100 (99-100)	0.0192

Conclusion

A decreased perfusion index value in the pre-anesthesia phase of elective cesarean section is a maternal predictor of increased neonatal morbidity and is significantly related to subclinical placental inflammatory disease. These observations suggest the feasibility of a noninvasive pulse oximeter prenatal screening of the high-risk fetus/newborn in elective cesarean section.

21 The Pulse Oximeter Perfusion Index as a Predictor for High Illness Severity in Neonates

De Felice C., Latini G., Vacca P., Kopotic R.J. *Eur J Pediatr*. 2002;161(10):561-2.

Introduction

The perfusion index (Pi) of a pulse oximeter is the pulsatile signal indexed against the non-pulsatile signal, expressed as a percentage (AC/DC X 100). Since this potential measure of peripheral perfusion does not require direct caregiver observation, which can be compromised by factors such as unpredictable skin coloration, its value as an assessment tool could be high. These researchers studied whether the perfusion index of the Masimo SET Radical could be used to assess the severity of neonatal illness.

Methods

Illness severity of 101 Caucasian infants was judged according to the Score for Neonatal Acute Physiology (SNAP) and each infant was placed into either the High Illness or Low Illness category. An operator who was unaware of the infant illness severity group captured Pi values generated by a Masimo SET oximeter at regular intervals. SpO_2, pulse rate, body temperature, and blood pressure were also measured.

According to the predefined criteria, 43 neonates were admitted to the high-severity group and 58 to the low-severity group. The high-severity group showed significantly higher severe neonatal morbidity. The receiver operating characteristic (ROC) curve was used to calculate the accuracy of the Pi, SpO_2, and pulse rate in predicting high illness severity.

Results

SpO_2 and pulse rate showed insufficient accuracy in predicting illness severity, while the Pi's predictive accuracy was shown to be significant, with 95.5% sensitivity, 93.7% specificity, 91.2% positive predictive value, and 96.8% negative predictive value.

	High Severity (43 neonates)	Low Severity (58 neonates)
Pi*	0.86 + 0.26	2.02 + 0.70
SpO_2*	93.3 + 5.4%	95.1 + 3.9%
Pulse Rate*	139 + 16 bpm	133 + 17 bpm

*p<0.0001

22 Goal-Directed Fluid Management Based on the Pulse Oximeter-Derived Pleth Variability Index Reduces Lactate Levels and Improves Fluid Management

Forget P., Lois F., de Kock M. *Anesth Analg*. 2010;111(4):910-4.

Background

Dynamic variables predict fluid responsiveness and may improve fluid management during surgery. We investigated whether displaying the variability in the pulse oximeter plethysmogram (Pleth Variability Index; PVi) would guide intraoperative fluid management and improve circulation as assessed by lactate levels.

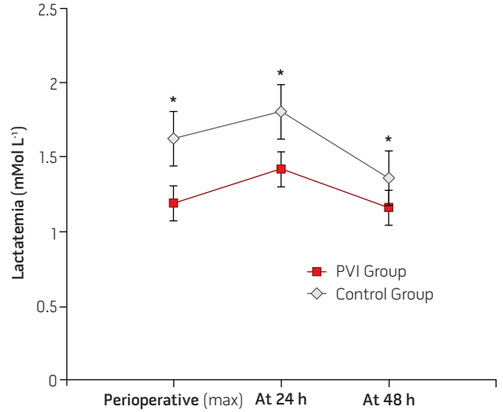
Methods

Eighty-two patients scheduled for major abdominal surgery were randomized into 2 groups to compare intraoperative PVi-directed fluid management (PVi group) versus standard care (control group). After the induction of general anesthesia, the PVi group received a 500 mL crystalloid bolus and a crystalloid infusion of 2 mL . kg(-1) . h(-1). Colloids of 250 mL were administered if the PVi was >13%. Vasoactive drug support was given to maintain the mean arterial blood pressure above 65 mm Hg. In the control group, an infusion of 500 mL of crystalloids was followed by fluid management on the basis of fluid challenges and their effects on mean arterial blood and central venous pressure. Perioperative lactate levels, hemodynamic data, and postoperative complications were recorded prospectively.

Results

Intraoperative crystalloids and total volume infused were significantly lower in the goal-directed PVi group. Lactate levels were significantly lower in the PVi group during surgery and 48 hours after surgery (p<0.05).

Lactate Levels During and After Surgery in the PVi-guided Group and Control Group



Conclusion

PVi-based, goal-directed fluid management reduced the volume of intraoperative fluid infused and reduced intraoperative and postoperative lactate levels.

Masimo-supported Study

23

M

Pleth Variability Index to Monitor the Respiratory Variations in the Pulse Oximeter Plethysmographic Waveform Amplitude and Predict Fluid Responsiveness in the Operating Theatre

Cannesson M., Desebbe O., Rosamel P., Delannoy B., Robin J., Bastien O., Lehot J.J. *Br J Anaesth*. 2008;101(2):200-6.

Background

Respiratory variations in pulse oximetry plethysmographic waveform amplitude (ΔPOP) can predict fluid responsiveness in mechanically ventilated patients but cannot be easily assessed at the bedside. Pleth variability index (PVi) is a new algorithm allowing for automated and continuous monitoring of ΔPOP. We hypothesized that PVi can predict fluid responsiveness in mechanically ventilated patients under general anaesthesia.

Methods

Twenty-five patients were studied after induction of general anaesthesia. Haemodynamic data {cardiac index [CI], respiratory variations in arterial pulse pressure [ΔPP], ΔPOP, and PVi} were recorded before and after volume expansion (500 mL of hetastarch 6%). Fluid responsiveness was defined as an increase in CI > or = 15%.

Results

Volume expansion induced changes in CI {2.0 [sd 0.9] to 2.5 [1.2] liter min[-1] m[-2]; $p<0.01$}, ΔPOP {15 [7]% to 8 [3]%; $p<0.01$}, and PVi {14 [7]% to 9 [3]%; $p<0.01$}. ΔPOP and PVi were higher in responders than in nonresponders {19 [9]% vs 9 [4]% and 18 [6]% vs 8 [4]%, respectively; $p<0.01$ for both}. A PVi >14% before volume expansion discriminated between responders and nonresponders with 81% sensitivity and 100% specificity. There was a significant relationship between PVi before volume expansion and change in CI after volume expansion ($r=0.67$; $p<0.01$).

Conclusion

PVi, an automatic and continuous monitor of ΔPOP, can predict fluid responsiveness noninvasively in mechanically ventilated patients during general anaesthesia. This index has potential clinical applications.

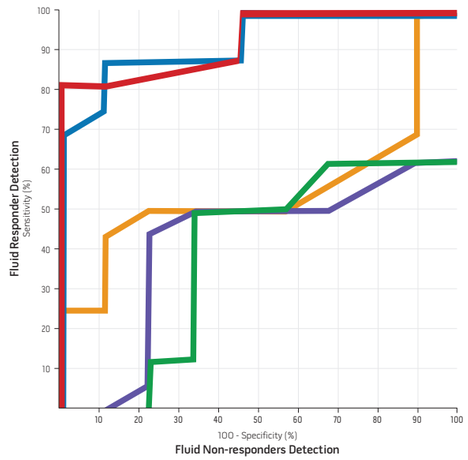


Figure 1: Receiver operating characteristic for hemodynamic measurements at baseline to discriminate between responders and nonresponders to volume expansion.

Adapted from Cannesson M. et al. Br J Anesth. 2008;101(2):200-6.

24

M

Pleth Variability Index Predicts Fluid Responsiveness in Critically Ill Patients

Loupec T., Nanadoumgar H., Frasca D., Petitpas F., Laksiri L., Baudouin D., Debaene B., Dahyot-Fizelier C., Mimoz O. *Crit Care Med*. 2011;39(2):294-9.

Objective

To investigate whether the pleth variability index, a noninvasive and continuous tool, can predict fluid responsiveness in mechanically ventilated patients with circulatory insufficiency.

Methods

Design: Prospective study. **Setting:** Surgical intensive care unit of a university hospital. **Patients:** Forty mechanically ventilated patients with circulatory insufficiency in whom volume expansion was planned by attending physician. Exclusion criteria included spontaneous respiratory activity, cardiac arrhythmia, known intracardiac shunt, severe hypoxemia (PaO_2/FiO_2 <100 mm Hg), contraindication for passive leg raising, left ventricular ejection fraction of <50%, and hemodynamic instability during the procedure. **Interventions:** Fluid challenge with 500 mL of 130/0.4 hydroxyethyl starch if respiratory variations in arterial pulse pressure were ≥13% or with passive leg raising if variations in arterial pulse pressure were <13%.

Results

Pleth variability index, variations in arterial pulse pressure, and cardiac output estimated by echocardiography were recorded before and after fluid challenge. Fluid responsiveness was defined as an increase in cardiac output of ≥15%. Twenty-one patients were responders and 19 were nonresponders. Mean ± SD pleth variability index (28% ± 13% vs 11% ± 4%) and arterial pulse pressure variation (22% ± 11% vs 5% ± 2%) values at baseline were significantly higher in responders than in nonresponders. The pleth variability index threshold value of 17% allowed discrimination between responders and nonresponders with a sensitivity of 95% (95% confidence interval, 74% to 100%) and a specificity of 91% (95% confidence interval, 70% to 99%). The pleth variability index at baseline correlated ($r = 0.72$, $p<0.0001$) with the percentage change in cardiac output induced by fluid challenge, suggesting that a higher pleth variability index at baseline will correlate with a higher percentage change in cardiac output after volume expansion.

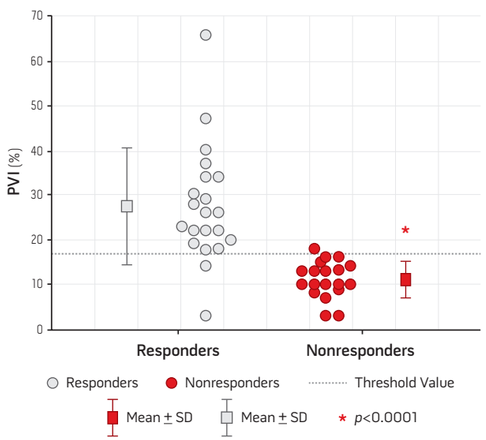


Figure 1: ROC curve for PVi, PPV, and CO at baseline to discriminate between responders and nonresponders to fluid challenge.

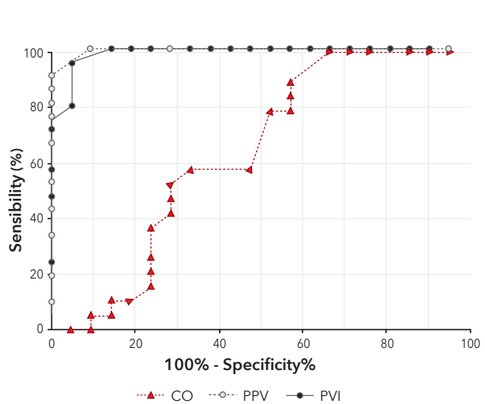


Figure 2: ROC curve for PVi, PPV, and CO at baseline to discriminate between responders and nonresponders to fluid challenge.

Conclusion

The pleth variability index can predict fluid responsiveness noninvasively in intensive care unit patients under mechanical ventilation.

25 Accuracy of Stroke Volume Variation Compared with Pleth Variability Index to Predict Fluid Responsiveness in Mechanically Ventilated Patients Undergoing Major Surgery

Zimmermann M, Feibicke T, Keyl C, Prasser C, Moritz S, Graf BM, Wiesenack C. *Eur J Anaesthesiol*. 2010;27(6):555-61.

Background and Objective

Accurate assessment of a patient's volume status is an important goal for an anesthetist. However, most variables assessing fluid responsiveness are either invasive or technically challenging. This study was designed to compare the accuracy of arterial pressure-based stroke volume variation (SVV) and variations in the pulse oximeter plethysmographic waveform amplitude as evaluated with the noninvasive calculated pleth variability index (PVi) with central venous pressure to predict the response of stroke volume index (SVI) to volume replacement in patients undergoing major surgery.

Methods

We studied 20 patients scheduled for elective major abdominal surgery. After induction of anesthesia, all haemodynamic variables were recorded immediately before (T1) and subsequent to volume replacement (T2) by infusion of 6% hydroxyethyl starch (HES) 130/0.4 (7 mL kg) at a rate of 1 mL kg min.

Results

The volume-induced increase in SVI was at least 15% in 15 patients (responders) and less than 15% in 5 patients (nonresponders). Baseline SVV correlated significantly with changes in SVI (delta SVI; r = 0.80; $p<0.001$) as did baseline PVi (r = 0.61; $p<0.004$), whereas baseline values of central venous pressure showed no correlation to delta SVI. There was no significant difference between the area under the receiver operating characteristic curve for SVV (0.993) and PVi (0.973). The best threshold values to predict fluid responsiveness were more than 11% for SVV and more than 9.5% for PVi.

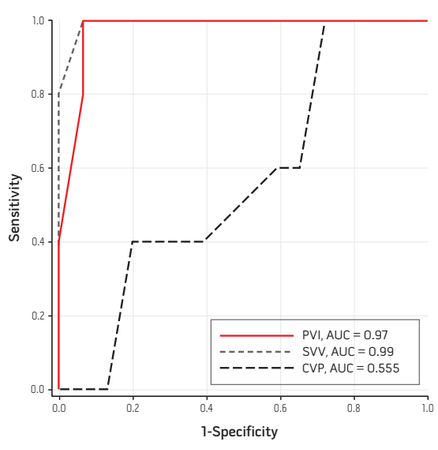


Figure 1: ROC curves comparing the ability of SVV, PVi, and CVP to predict a volume-induced increase in stroke volume index more than 15%.

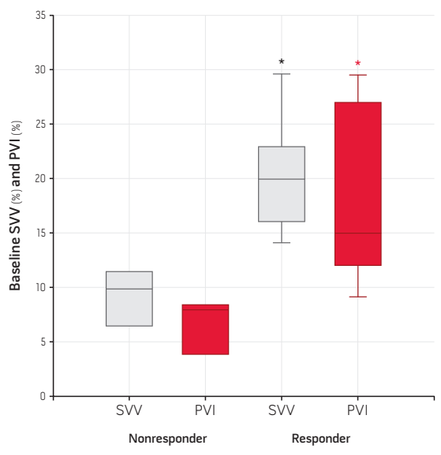


Figure 2: Median values and interquartile range of baseline values of stroke SVV and PVi in responders and nonresponders. *p<0.001 vs nonresponders.

Conclusion

Although arterial pressure-derived SVV revealed the best correlation to volume-induced changes in SVI, the results of our study suggest that both variables, SVV and PVi, can serve as valid indicators of fluid responsiveness in mechanically ventilated patients undergoing major surgery.

26 Stroke Volume Variation and Pleth Variability Index to Predict Fluid Responsiveness During Resection of Primary Retroperitoneal Tumors in Hans Chinese

Fu Q, Mi WD, Zhang H. *Biosci Trends*. 2012;6(1):38-43.

Introduction

Respiration variation in arterial pulse pressure (PP) and pulse oximetry plethysmographic waveform amplitude (POP) are accurate predictors of fluid responsiveness in mechanically ventilated patients. We hypothesized that stroke volume variation (SVV) and pleth variability index (PVi) can predict fluid responsiveness in mechanically ventilated patients during major surgical procedures in Hans Chinese.

Methods

This prospective study consisted of 55 Hans Chinese patients undergoing resection of primary retroperitoneal tumors (PRPT). During the surgical procedures, hemodynamic data {central venous pressure [CVP], cardiac index [CI], stroke volume index [SVI], SVV, and PVi} were recorded before and after volume expansion (VE) (8 mL•kg-1 of 6% hydroxyethylstarch 130/0.4). Fluid responsiveness was defined as an increase in SVI ≥10% after VE.

Results

Four patients were excluded from analysis for arrhythmia or obvious hemorrhage during VE. Baseline SVV correlated well with baseline PVi and the changes in SVV correlated with the changes in PVi ($p<0.01$) after VE. There were significant increases of CI, SVI and decreases of SVV, PVi in responder (Rs) after VE. ROC results showed that the areas for SVV, PVi were significantly higher than the areas for CI, MAP, CVP, PI ($p<0.05$). The best threshold values to predict fluid responsiveness were more than 12.5% for SVV and more than 13.5% for PVi in the real surgical setting.

ROC Curves and Cutoff Values of Various Hemodynamic Parameters for Prediction of Fluid Responsiveness

	Optimal Threshold Value	Sensitivity (%)	Specificity (%)	AUC (95% CI)	*p* Value
SVV	12.5%	87.9	83.3	0.862 (0.761-0.963)	0.001
PVi	13.5%	77.4	80.0	0.785 (0.651-0.920)	0.002
SVI	43.5 mL•m^{-2}	83.3	91.0	0.726 (0.577-0.875)	0.057
CI	2.85 Liter min^{-1}•m^{-2}	72.2	75.8	0.651 (0.488-0.813)	0.071
CVP	7.5 mmHg	61.1	63.6	0.606 (0.447-0.779)	0.203

Conclusion

The baseline value of SVV and PVi correlated significantly with volume-induced changes in SVI ($p<0.01$). Both SVV and PVi could be used to predict intraoperative fluid responsiveness during resection of PRPT in Hans Chinese.

27 Prediction of Volume Responsiveness Using Pleth Variability Index in Patients Undergoing Cardiac Surgery After Cardiopulmonary Bypass

Haas S, Trepte C, Hinteregger M, Fahje R, Sill B, Herich L, Reuter DA. *J Anesth*. 2012 Oct;26(5):696-701.

Background

The pleth variability index (PVi) is derived from analysis of the plethysmographic curve and is considered to be a noninvasive parameter for prediction of volume responsiveness. The aim of our prospective clinical study was to evaluate if volume responsiveness can be predicted by PVi in patients undergoing cardiac surgery after cardiopulmonary bypass.

Methods

Eighteen patients were prospectively studied. Directly after cardiac surgery, PVi, stroke volume variation (SVV), and cardiac index (CI) were recorded. Colloid infusion (4 mL/kg body weight) was used for volume loading, and volume responsiveness was defined as increase of CI more than 10%.

Results

SVV and PVi measures were found to be highly correlated at r = 0.80 (p<0.001). Receiver operating characteristics curve (ROC) analysis resulted in an area under the curve of 0.87 for SVV and 0.95 for PVi, which values did not differ statistically significant from each other (p>0.05). The optimal threshold value given by ROC analysis was ≥11% for SVV with a sensitivity and specificity of 100% and 72.2%. For PVi, optimal threshold value was ≥16% with a sensitivity and specificity of 100% and 88.9%. Positive and negative predictive values estimating an increase of CI ≥10% for SVV were 44.4% and 100% and 66.7% and 100% for PVi.

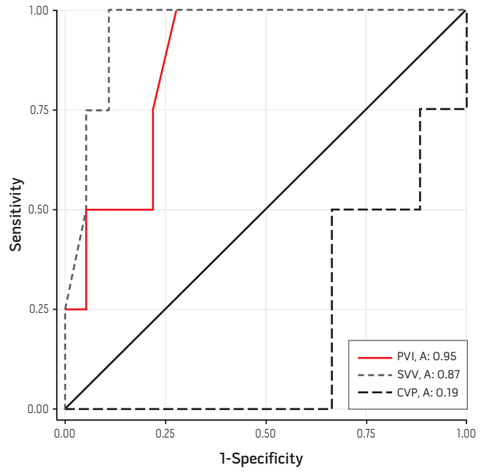


Figure 1: ROC curves comparing the ability of SVV, PVi, and central venous pressure (CVP) to predict an increase of CI of more than 10%

Conclusion

For consideration of fluid responsiveness, PVi is as accurate as SVV in patients after cardiopulmonary bypass. Methodological limitations, such as instable cardiac rhythm after cardiopulmonary bypass and right or left ventricular impairment, seem to be responsible for low specificity and positive predictive values in both parameters PVi and SVV.

28 Prediction of Fluid Responsiveness in Mechanically Ventilated Children Undergoing Neurosurgery

Byon HJ, Lim CW, Lee JH, Park YH, Kim HS, Kim CS, Kim JT. *Br J Anaesth*. 2013 Apr;110(4):586-91.

Background

The purpose of this study was to evaluate the clinical usefulness of static and dynamic variables for the prediction of fluid responsiveness in children under general anaesthesia.

Methods

Thirty-three mechanically ventilated children received 10 mL/kg colloid for 10 min while stable during surgery. Arterial pressure, heart rate, central venous pressure (CVP), and pleth variability index (PVi), in addition to variation in systolic pressure, pulse pressure (including Δdown and Δup), respiratory aortic blood flow velocity (ΔVpeak), and inferior vena cava diameter were measured before and after volume expansion. Patients were classified as responders to fluid loading if their stroke volume index (SVI) increased by at least 10%.

Results

There were 15 volume responders and 18 nonresponders. Of the variables examined, ΔVpeak (r=0.516, p=0.004) and PVi (r=0.49, p=0.004) before volume expansion were significantly correlated with changes in SVI. The receiver operating characteristic (ROC) curve analysis showed that PVi and DVpeak predicted fluid responsiveness. Areas under the ROC curves of PVi and ΔVpeak were statistically larger than that of CVP (p=0.006 and 0.014, respectively). However, those of other variables were similar to that of CVP.

Comparison of Areas Under ROC Curves Before Volume Expansion

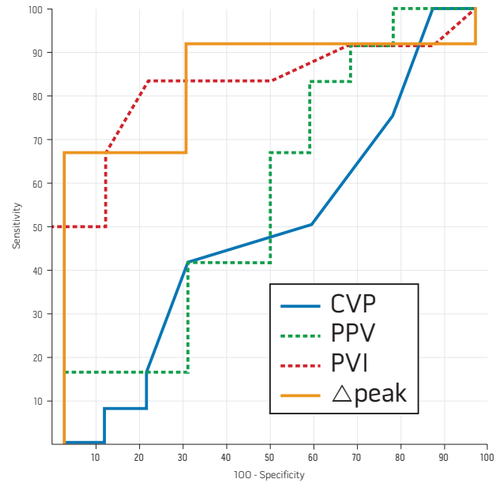


Figure 1: Areas under the ROC curve of DVpeak and PVi are significantly larger than that of CVP before fluid loading (p=0.006 and 0.014, respectively).

Conclusion

ΔVpeak and PVi can be used to predict fluid responsiveness in mechanically ventilated children under general anaesthesia. The other static and dynamic variables assessed in this study were not found to predict fluid responsiveness significantly in children.

29 The Ability of Pleth Variability Index to Predict the Hemodynamic Effects of Positive End Expiratory Pressure in Mechanically Ventilated Patients under General Anesthesia

Desebbe O, Boucau C, Farhat F, Bastien O, Lehot JJ, Cannesson M. *Anesth Analg*. 2010 Mar 1;110(3):792-8.

Background

Pleth variability index (PVi) is a new algorithm allowing automated and continuous monitoring of respiratory variations in the pulse oximetry plethysmographic waveform amplitude. PVi can predict fluid responsiveness noninvasively in mechanically ventilated patients during general anesthesia. We hypothesized that PVi could predict the hemodynamic effects of 10 cm H_2O positive end-expiratory pressure (PEEP).

Methods

We studied 21 mechanically ventilated and sedated patients in the postoperative period after coronary artery bypass grafting. Patients were monitored with a pulmonary artery catheter and a pulse oximeter sensor attached to the index finger. Hemodynamic data (cardiac index [CI], PVi, pulse pressure variation, central venous pressure) were recorded at 3 successive tidal volumes (V(T)) (6, 8, and 10 mL/kg body weight) during zero end-expiratory pressure (ZEEP) and then after addition of a 10 cm H_2O PEEP for each V(t). Hemodynamically unstable patients were defined as those with a >15% decrease in CI after the addition of PEEP.

Results

PEEP induced changes in CI and PVi for V(t) of 8 and 10 mL/kg. Hemodynamic instability occurred in 5 patients for a V(T) of 6 mL/kg, in 6 patients for a V(T) of 8 mL/kg, and in 9 patients for a V(T) of 10 mL/kg. For V(T) of 8 mL/kg, a PVi threshold value of 12% during ZEEP predicted hemodynamic instability with a sensitivity of 83% and a specificity of 80% (area under the receiver operating characteristic curve 0.806; P = 0.03). For V(T) of 10 mL/kg, a PVi threshold value of 13% during ZEEP predicted hemodynamic instability with a sensitivity of 78% and a specificity of 83% (area under the receiver operating characteristic curve 0.829; P = 0.01).

Conclusion

PVi may be useful in automatically and noninvasively detecting the hemodynamic effects of PEEP when V(T) is >8 mL/kg in ventilated and sedated patients with acceptable sensitivity and specificity.

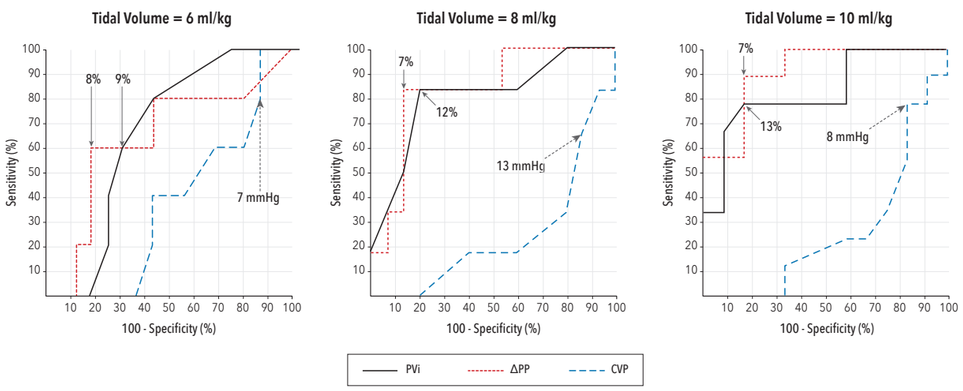


Figure 1: Sensitivity and specificity of PVi, Pulse Pressure Variation and Central Venous Pressure to predict hemodynamic instability induced by PEEP

30 Pleth Variability Index Predicts Hypotension During Anesthesia Induction

Tsuchiya M(1), Yamada T, Asada A. *Acta Anaesthesiol Scand*. 2010 May;54(5):596-602.

Background

The pleth variability index (PVi) is a new algorithm used for automatic estimation of respiratory variations in pulse oximeter waveform amplitude, which might predict fluid responsiveness. Because anesthesia-induced hypotension may be partly related to patient volume status, we speculated that pre-anesthesia PVi would be able to identify high-risk patients for significant blood pressure decrease during anesthesia induction.

Methods

We measured the PVi, heart rate (HR), systolic blood pressure (SBP), diastolic blood pressure (DBP), and mean arterial pressure (MAP) in 76 adult healthy patients under light sedation with fentanyl to obtain pre-anesthesia control values. Anesthesia was induced with bolus administrations of 1.8 mg/kg propofol and 0.6 mg/kg rocuronium. During the 3-min period from the start of propofol administration, HR, SBP, DBP, and MAP were measured at 30-s intervals.

Results

HR, SBP, DBP, and MAP were significantly decreased after propofol administration by 8.5%, 33%, 23%, and 26%, respectively, as compared with the pre-anesthesia control values. Linear regression analysis that compared pre-anesthesia PVi with the decrease in MAP yielded an r value of -0.73. Decreases in SBP and DBP were moderately correlated with pre-anesthesia PVi, while HR was not. By classifying PVi >15 as positive, a MAP decrease >25 mmHg could be predicted, with sensitivity, specificity, positive predictive, and negative predictive values of 0.79, 0.71, 0.73, and 0.77, respectively.

Conclusion

Pre-anesthesia PVi can predict a decrease in MAP during anesthesia induction with propofol. Its measurement may be useful to identify high-risk patients for developing severe hypotension during anesthesia induction.

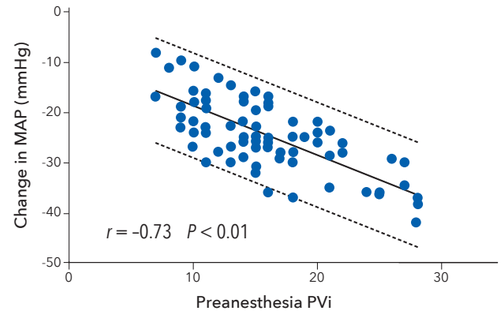


Figure 1: Correlation and linear regression of pre-anesthesia PVi with the magnitude of maximum change in MAP after propofol administration.

31 Plethysmographic Variation Index Predicts Fluid Responsiveness in Ventilated Patients in the Early Phase of Septic Shock in the Emergency Department: A Pilot Study

Feissel M, Kalakhy R, Banwarth P, Badie J, Pavon A, Faller JP, Quenot JP. *J Crit Care*. 2013 Oct;28(5):634-9.

Purpose

Feasibility study examining whether plethysmographic variability index (PVi) can predict fluid responsiveness in mechanically ventilated patients in the early phase of septic shock in the emergency department.

Materials and Methods

Monocentric, prospective, observational study that included 31 mechanically ventilated and sedated patients with septic shock in whom volume expansion was planned. The patients were equipped with a pulse oximeter that automatically calculated and displayed PVi. The intervention consisted in infusing 8 mL/kg of hydroxylethyl starch over a 20-minute period. Before and after intervention, we recorded PVi and measured the aortic velocity-time integral (VTIao) using transthoracic echocardiography. Responders were defined as patients who increased their VTIao by 15% or higher after fluid infusion.

Results

Sixteen patients were classified as responders, and 15 as nonresponders. Mean PVi values before intervention were significantly higher in responders vs nonresponders (30%±9% vs 8%±5%, P<.001). Plethysmographic variability index values before intervention were correlated with percent changes in VTIao induced by intervention (R2=0.67; P<.001). A PVi threshold value of 19% discriminates responders from nonresponders with a sensitivity of 94% and a specificity of 87% (area under the curve, 0.97; P<.001).

Conclusion

Our study suggests that PVi is a feasible and interesting method to predict fluid responsiveness in early phase septic shock patients in the emergency department.

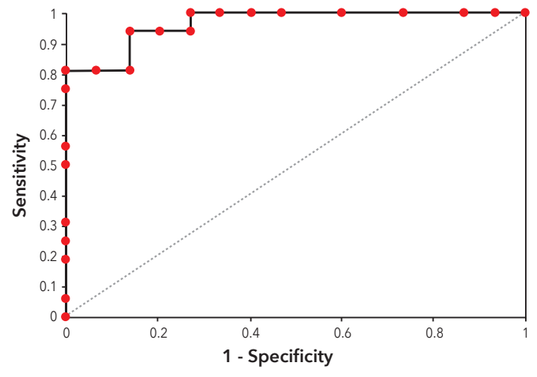


Figure 1: Receiver operating characteristic curve identifying threshold value of 19% to distinguish responder from non-responders to fluid challenge.

32 Pleth Variability Index-Directed Fluid Management in Abdominal Surgery under Combined General and Epidural Anesthesia

Yu Y., Dong J., Xu Z., Shen H., Zheng J. *J Clin Monit Comput*. 2014 Feb 21.

Pleth variability index (PVi), a noninvasive dynamic indicator of fluid responsiveness has been demonstrated to be useful in the management of the patients with goal directed fluid therapy under general anesthesia, but whether PVi can be used to optimize fluid management under combined general and epidural anesthesia (GEN-EPI) remains to be elucidated. The aim of our study was to explore the impact of PVi as a goal-directed fluid therapy parameter on the tissue perfusion for patients with GENEPI. Thirty ASA I-II patients scheduled for major abdominal surgeries under GEN-EPI were randomized into PVI-directed fluid management group (PVi group) and non PVi-directed fluid management group (control group). 2 mL/kg/h crystalloid fluid infusion was maintained in PVi group, once PVi > 13 %, a 250 mL colloid or crystalloid was rapidly infused. 4-8 mL/kg/h crystalloid fluid infusion was maintained in control group, and quick fluid infusion was initiated if mean arterial blood pressure (BP) < 65 mmHg. Small doses of norepinephrine were given to keep mean arterial BP above 65 mmHg as needed in both groups. Perioperative lactate levels, hemodynamic changes were recorded individually. The total amount of intraoperative fluids, the amount of crystalloid fluid and the first hour blood lactate levels during surgery were significantly lower in PVi than control group, P < 0.05. PVi-based goal-directed fluid management can reduce the intraoperative fluid amount and blood lactate levels in patients under GEN-EPI, especially the crystalloid. Furthermore, the first hour following GEN-EPI might be the critical period for anesthesiologist to optimize the fluid management

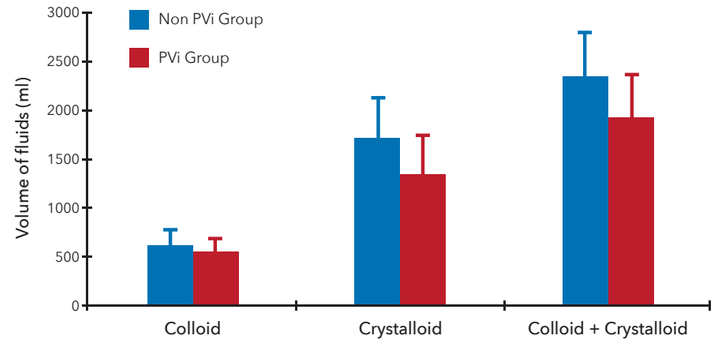


Figure 1: Fluids administered during anesthesia in the PVI-guided fluid therapy group and the Control group.

33 Influence of the Site of Measurement on the Ability of Plethysmographic Variability Index to Predict Fluid Responsiveness

Desgranges F.P., Desebbe O., Ghazouani A., Gilbert K., Keller G., Chiari P., Robin J., Bastien O., Lehot J.J., Cannesson M.
Br. J. Anaesth 2011 Sep;107(3):329-35.

Background

Plethysmographic variabilit2011 Sep;107(3):329-35. y index (PVi) is an accurate predictor of fluid responsiveness in mechanically ventilated patients. However, the site of measurement of the plethysmographic waveform impacts its morphology and its respiratory variation. The goal of this study was to investigate the ability of PVi to predict fluid responsiveness at three sites of measurement (the forehead, ear, and finger) in mechanically ventilated patients under general anaesthesia.

Methods

We studied 28 subjects after induction of general anaesthesia. Subjects were monitored with a pulmonary artery catheter and three pulse oximeter sensors (the finger, ear, and forehead). Pulse pressure variation, central venous pressure, cardiac index (CI), and PVi measured at the forehead, ear, and finger (PVIforehead, PVIear, and PVIfinger) were recorded before and after fluid loading (FL). Subjects were responders to volume expansion if CI increased .15% after FL.

Results

Areas under the receiver-operating curves to predict fluid responsiveness were 0.906, 0.880, and 0.836 for PVIforehead, PVIear, and PVIfinger, respectively (P,0.05). PVIforehead, PVIear, and PVIfinger had a threshold value to predict fluid responsiveness of 15%, 16%, and 12% with sensitivities of 89%, 74%, and 74% and specificities of 78%, 74%, and 67%, respectively.

Conclusion

PVi can predict fluid responsiveness in anaesthetized and ventilated subjects at all three sites of measurement. However, the threshold values for predicting fluid responsiveness differ with the site of measurement. These results support the use of this plethysmographic dynamic index in the cephalic region when the finger is inaccessible or during states of low peripheral perfusion.

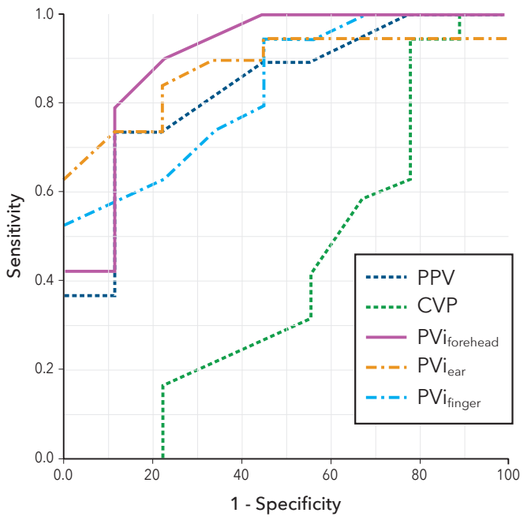


Figure 1: ROC curves comparing the ability of PVi recorded at the forehead, ear, and finger, automated PPV and CVP at baseline to discriminate between responders and non-responders.

34 Impact of Skin Incision on the Pleth Variability Index

Takeyama M, Matsunaga A, Kakihana Y, Masuda M, Kuniyoshi T, Kanmura Y. *J Clin Monit Comput* 2011 Aug;25(4):215-21.

Objective

The pleth variability index (PVi), which is calculated from respiratory variations in the perfusion index (Pi), reportedly predicts fluid responsiveness. However, vasomotor tone fluctuations induced by nociceptive stimuli change the PI and may reduce the accuracy of PVi. The aim of this study was to confirm the effects of surgical stimuli on PVi.

Methods

Twenty-four patients were examined after the induction of general anesthesia. Heart rate (HR), mean arterial blood pressure (MBP), Pi, PVi, stroke volume variation (SVV), and cardiac index (CI) were recorded before and after the skin incision. Pi and PVi were calculated using a Radical 7 pulse oximeter, and SVV and CI were calculated using the FloTrac/ Vigileo system.

Results

After the skin incision, the Pi decreased significantly from 5.3 (4.0–6.2%) to 3.6% (1.8– 4.7%), whereas the PVi increased significantly from 9.5 (7.0– 12.0%) to 13.5% (9.0–16.0%). A significant negative correlation was observed between the changes in Pi and PVi before and after the skin incision. The skin incision did not affect the HR, CI, or SVV but increased the MBP.

Conclusion

This study showed a significant increase in the PVi and a negative correlation between the changes in PVi and Pi before and after the skin incision. The PVi can be calculated from the variations in the Pi caused not by mechanical ventilation, but rather by fluctuations in vasomotor tone. When using the PVi as an indicator for fluid responsiveness, it is crucial to pay attention to fluctuations in vasomotor tone induced by nociceptive stimuli.

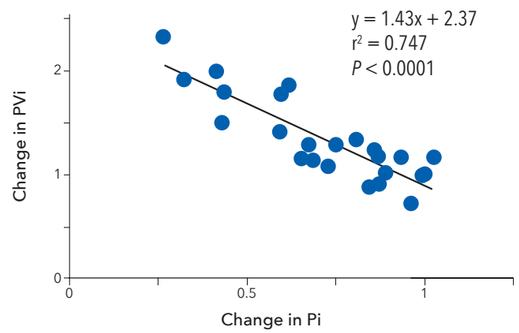


Figure 1: Correlation between the changes in the Pi and the PVi before and at 1 min after skin incision. The changes in the Pi and the PVi are represented as the ratio of the Pi and the PVi value observed after skin incision to the value observed before skin incision, respectively.

35 Impact of Pulse Oximetry Surveillance on Rescue Events and Intensive Care Unit Transfers: A Before-and-After Concurrence Study

Taenzer AH, Pyke JB, McGrath SP, Blike GT. *Anesthesiology*. 2010;112(2):282-7.

Background

Some preventable deaths in hospitalized patients are due to unrecognized deterioration. There are no publications of studies that have instituted routine patient monitoring postoperatively and analyzed impact on patient outcomes.

Methods

The authors implemented a patient surveillance system based on pulse oximetry with nursing notification of violation of alarm limits via wireless pager. Data were collected for 11 months before and 10 months after implementation of the system. Concurrently, matching outcome data were collected on 2 other postoperative units. The primary outcomes were rescue events and transfers to the intensive care unit compared before and after monitoring change.

Results

Rescue events decreased from 3.4 (1.89-4.85) to 1.2 (0.53-1.88) per 1000 patient discharges and intensive care unit transfers from 5.6 (3.7-7.4) to 2.9 (1.4-4.3) per 1000 patient days, whereas the comparison units had no change.

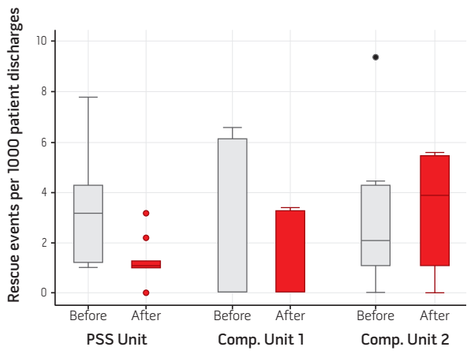


Figure 1: Rescue Events Per 1000 Patient Discharges Before and After Patient Surveillance System Unit.

Figure 2: Transfers to ICU on the PSS Unit per 1000 Patient Days Before and After Implementation.

Conclusion

Patient surveillance monitoring results in a reduced need for rescues and intensive care unit transfers.

36 Postoperative Monitoring – The Dartmouth Experience

Taenzer AH, Blike GT. *APSF Newsletter*. 2012;27(1):1-28. Available at http://www.apsf.org/newsletters/html/2012/spring/01_postop.htm. Accessed June 14, 2012.

Introduction

The purpose of this study was to quantify the results of expanding the use of Masimo SET Measure-through Motion and Low Perfusion pulse oximetry and Patient SafetyNet remote monitoring and clinician notification system from a single orthopedic postsurgical unit to all medical and surgical units at Dartmouth Hitchcock Medical Center.

Methods

A patient surveillance system based on pulse oximetry with nursing notification of violation of alarm limits via wireless pager was implemented on all medical and surgical units at Dartmouth Hitchcock Medical Center following an initial implementation on a single orthopedic postsurgical unit. The study tested: a) if alarm settings for heart rate (HR) and oxygen saturation (SpO_2) were transferable among different surgical populations or between surgical and medical populations, b) if the initially reported results from the single orthopedic postsurgical unit of reductions in rescue events and transfers to the intensive care unit were reproducible on other units, and c) if patient surveillance is cost-effective. Cost effectiveness was analyzed based on reduction of ICU transfers and days spent in ICU.

Result

Since the implementation of continuous monitoring of 100% of patients on all Medical and Surgical units using Patient SafetyNet in 2010, there was as great as 65% reduction in rescue events and as great as 50% reduction in ICU transfers in individual units. Additionally, there was a 57% overall reduction in rescue events over all surgical units (4.4 to 1.9 per 1000 patient days per month). No patients suffered irreversible severe brain damage or died as a result of respiratory depression from opioids since patient surveillance was instituted on the original study unit in December 2007. Medical units did not recognize the gains that the surgical units did. Contributing factors included a low event rate at baseline and the fact that the majority of rescue events (>75%) are respiratory in nature caused by opioid consumption, which is greater on surgical units than on medical units.

Cost effectiveness analysis showed $1.48 million in annual opportunity cost savings in the original orthopedic unit due to the decreased ICU transfer rate (compared to initial costs just $167,993 for equipment and training and annual operational costs of just $58,261 for implementation and disposable sensors). $58,459 was saved per patient who was not transferred to the ICU in the original orthopedic unit ($76,044 vs $17,585). There was a 21% decrease in average length of stay of a patient with transfer to the ICU (total 5.1 days decreased, 1.8 days in the ICU and 3.3 days on the general floor) in the original orthopedic unit. Sixty-eight ICU days were saved in the thora CO-vascular unit in the first 12 months after implementation. Per patient monitoring cost was $85 for the first year of implementation and $22 thereafter.

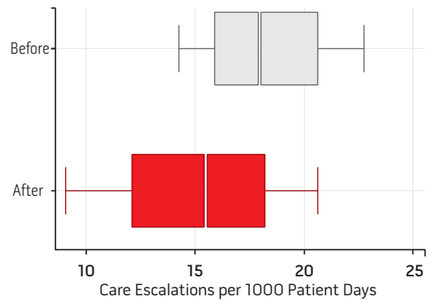


Figure 1: Rescue events per 1000 patient days per month over 2 years with patient surveillance deployment after 12 months on 3 surgical units.

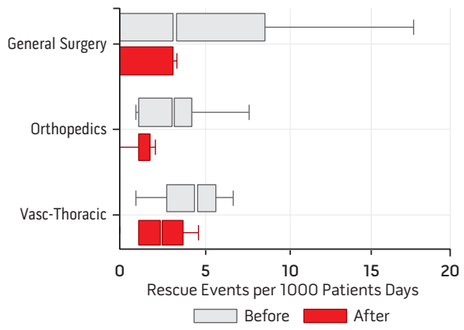


Figure 2: Care escalations per 1000 patient pays per month in the 12 months before and after implementation of patient surveillance.

Conclusion

The expansion of Masimo SET and Patient SafetyNet had positive outcomes on all Surgical Units, confirming the results of the initial study and demonstrating that those results are reproducible on additional postsurgical floors. Cost effectiveness of monitoring of 100% of patients was demonstrated in both reduction in rescue events and ICU transfers, and in workflow improvements that increased patient throughput and capacity.

37 Surveillance Monitoring Management for General Care Units: Strategy, Design, and Implementation

McGrath SP, Taenzer AH, Karon N, Blike G. Jt Comm J Qual Patient Saf. 2016 Jul;42(7):293-302.

Background

The growing number of monitoring devices, combined with suboptimal patient monitoring and alarm management strategies, has increased "alarm fatigue," which have led to serious consequences. Most reported alarm management approaches have focused on the critical care setting. Since 2007 Dartmouth-Hitchcock (Lebanon, New Hamp- shire) has developed a generalizable and effective design, implementation, and performance evaluation approach to alarm systems for continuous monitoring in general care settings (that is, patient surveillance monitoring).

Methods

In late 2007, a patient surveillance monitoring system was piloted on the basis of a structured design and implementation approach in a 36-bed orthopedics unit. Beginning in early 2009, it was expanded to cover more than 200 inpatient beds in all medicine and surgical units, except for psychiatry and labor and delivery.

Results

Improvements in clinical outcomes (reduction of unplanned transfers by 50% and reduction of rescue events by more than 60% in 2008) and approximately two alarms per patient per 12-hour nursing shift in the original pilot unit have been sustained across most D-H general care units in spite of increasing patient acuity and unit occupancy. Sample analysis of pager notifications indicates that more than 85% of all alarm conditions are resolved within 30 seconds and that more than 99% are resolved before escalation is triggered.

Conclusion

The D-H surveillance monitoring system employs several important, generalizable features to manage alarms in a general care setting: alarm delays, static thresholds set appropriately for the prevalence of events in this setting, directed alarm annunciation, and policy-driven customization of thresholds to allow clinicians to respond to needs of individual patients. The systematic approach to design, implementation, and performance management has been key to the success of the system.

Percentage of Rescue Events with Surveillance Data in Pilot Surveillance Unit and Entire Hospital, July 2014–January 2016

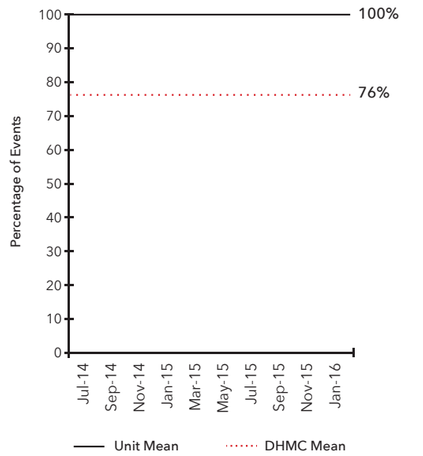


Figure 1: The six-month rolling average of rescue events that had surveillance data at least 30 minutes prior to the event (as of September 2015) is shown. The six-month rolling average measure is used because of low occurence rates. DHMC, Dartmouth-Hitchcock Medical Center.

02: Pulse CO-Oximetry

SpHb is not intended to replace laboratory blood testing. Blood samples should be analyzed by laboratory instruments prior to clinical decision making.

38

A

Abstract: Impact of Continuous Perioperative SpHb Monitoring

Nathan N, Ponsonnard S, Yonnet S, Dalmay F, Marin B, Drouet A. *Anesthesiology*. 2016;A1103

Background

Anemia and inadequate volume filling are two important factors that contribute to anesthesia-related mortality. The use of adequate monitoring of vascular filling predictive responsiveness has been proved to reduce mortality in prospective randomized studies. This may not be true if used in an uncontrolled setting such as found in common clinical practice. This study aimed to determine at a scale of a whole hospital if continuous monitoring of hemoglobin (SpHb) and PVI (plethysmography variability index) integrated in an algorithm could improve mortality and transfusion needs.

Methods

After ethical committee approval, this prospective single center observational study compared the % of patients receiving transfusion during the first postoperative 48H (primary criterion of judgement) and the mortality at 30 days and 90 days (secondary criteria) between two same periods in 2013 and 2014 (February 7 to December 31). During the 2014 period, all operating rooms (OR), recovery rooms and intensive care units were equipped with Radical 7® (Masimo, Irvine, USA) to monitor SpHb and PVI. Patients received vascular filling with crystalloids or blood according to an algorithm. The Operating Room and Intensive Care Clinical Team was trained to use the monitor and algorithm. Demographic, anesthesia, surgical and transfusion data were available from electronic files. When a patient had several surgeries during the same stay, only the first surgery was used for statistical analysis. Data issued from Radical-7® monitors was collected from SafetyNet™ (Masimo, Irvine, USA) secure system. Data were compared between the 2 years with statistical appropriate tests (SAS 9.1.3). The influence of different factors on mortality was analyzed with a cox-proportional hazard model. P < 0.05 was considered statistically significant.

	J 30		J 90	
	P	OR [IC 95%]	P	OR [IC 95%]
SpHb/PVi monitoring	0.0426	0.7 [0.50–0.99]	0.0366	0.75 [0.58–0.98]
Ages	0.0319 (61–70 years)	4.92 [1.15–21.13]	0.0001	15.99 [3.87–66.1]
	0.0004 (71–80 years)	13.4 [3.19–56.22]	< 0.0001	24.58 [5.95–101.57]
	0.0001 (81–90 years)	16.14 [3.84–67.76]	< 0.0001	36.19 [8.79–149.03]
Emergency surgery	< 0.0001	2.76 [1.93–3.95]	< 0.0001	2.21 [1.66–2.94]
Length of surgery	0.0029 (4h–6h)	4.58 [1.68–12.46]	0.1994	1.45 [0.82–2.55]
	< 0.0001 (> 6h)	10.35 [3.81–29.20]	0.0005	2.89 [1.59–5.26]
Transfusion at 48 H	< 0.0001	3.71 [2.53–5.44]	< 0.0001	3.48 [2.57–4.72]

Table 1: Adjusted mortality according to the cox-proportional hazard model (Wald: p=0.0001).

Results

Among the 18 867 patients included, SpHb and PVI data of 3540 patients were collected by the SafetyNet™ system in 2014. Proportion of transfused patients at 48H did not change between the 2 periods (7.9 % vs 8.5 %, 2013 vs 2014 p = 0.1323). It was also proportionality same for the number of blood units in transfused patients at 48H (3.4 ± 2.7 vs 3.4 ± 2.9, p >0.05). Among them, patients were transfused in the operating room and thus earlier when SpHb was used in non-cardiac surgery (72.9 % vs 56.1 %, p = 0.0002). According to the cox proportional hazard ratio, patients who were given blood or vascular filling according to the results of SpHb and PVI had a lower risk of death at 30 days (table 1).

Discussion

Monitoring SpHb and PVI integrated in a vascular filling algorithm allowed earlier transfusion and reduces mortality at a scale of a whole hospital with different clinical practices (and practitioners) and unselected patients.

39

Continuous Noninvasive Hemoglobin Monitoring during Orthopedic Surgery: A Randomized Trial

Ehrenfeld JM, Henneman JP, Bulka CM, Sandberg WS (2014). *J Blood Disorders Transf* 5:237.

Abstract

Blood transfusions during orthopedic surgery increase the risk of adverse outcomes and are costly. In current practice, laboratory hemoglobin values are used to determine the need for blood transfusion, but testing is intermittent. We hypothesized that continuous non-invasive hemoglobin monitoring (SpHb) could reduce intraoperative blood transfusions. Patients undergoing elective orthopedic surgery were randomized to receive standard care alone or standard care with SpHb monitoring. Of the 327 patients enrolled (170 intervention, 157 control), 0.6% received intraoperative transfusions in the intervention group compared to 4.5% in the control group, for an absolute risk reduction of 4% (95% CI: -7% to -0.4%). The amount of red blood cell units transfused did not differ between the groups, nor did the rate of laboratory hemoglobin testing. The use of continuous noninvasive hemoglobin monitoring may reduce the rate of transfusions when compared to standard care using intermittent laboratory hemoglobin testing.

	Retrospective Cohort (*N*=157)		Standard Care Group (*N*=157)		Differences	95% CI
Intraoperative		Total*		Total*		
Recieved RBC transfusions, *N* (%)	9 (5.7)	157	7 (4.5)	157	0.01	(-0.04, 0.06)
RBC units transfused, Median (Range)	0 (0-3)	157	0 (0-5)	157	0.00	(0.00, 0.00)

*Total refers to the number of patients for whom relevant data was available (e.g. responded to follow up). For categorical variables, difference refers to the risk difference.

For normally distributed continuous variables, difference refers to the difference in means. For skewed continous variables, difference refers to the difference in medians.

Table 3: Intraoperative outcomes among the Standard Care Group (control) and the matched retrospective cohort.

Masimo-supported Study

40

Continuous and Noninvasive Hemoglobin Monitoring Reduces Red Blood Cell Transfusion During Neurosurgery: A Prospective Cohort Study

Awada WN(1), Mohmoued MF, Radwan TM, Hussien GZ, Elkady HW. *J Clin Monit Comput*. 2015 Feb 4.
Author information: (1)Department of Anesthesia, ICU and Pain Management, Cairo University, Manyal, Cairo, Egypt, waoool@hotmail.com.

Background

Continuous, noninvasive hemoglobin (SpHb) monitoring provides clinicians with the trending of changes in hemoglobin, which has the potential to alter red blood cell transfusion decision making. The objective of this study was to evaluate the impact of SpHb monitoring on blood transfusions in high blood loss surgery. In this prospective cohort study, eligible patients scheduled for neurosurgery were enrolled into either a Control Group or an intervention group (SpHb Group). The Control Group received intraoperative hemoglobin monitoring by intermittent blood sampling when there was an estimated 15 % blood loss. If the laboratory value indicated a hemoglobin level of ≤10 g/dL, a red blood cell transfusion was started and continued until the estimated blood loss was replaced and a laboratory hemoglobin value was >l0 g/dL. In the SpHb Group patients were monitored with a Radical-7 Pulse CO-Oximeter for continuous noninvasive hemoglobin values. Transfusion was started when the SpHb value fell to ≤l0 g/dL and was continued until the SpHb was ≥l0 g/dL. Blood samples were taken pre and post transfusion. Percent of patients transfused, average amount of blood transfused in those who received transfusions and the delay time from the hemoglobin reading of <10 g/dL to the start of transfusion (transfusion delay) were compared between groups. The trending ability of SpHb, and the bias and precision of SpHb compared to the laboratory hemoglobin were calculated. Compared to the Control Group, the SpHb Group had fewer units of blood transfused (1.0 vs 1.9 units for all patients; p ≤ 0.001, and 2.3 vs 3.9 units in patients receiving transfusions; p ≤ 0.0 l), fewer patients receiving >3 units (32 vs 73 %; p ≤ 0.01) and a shorter time to transfusion after the need was established (9.2 ± 1.7 vs 50.2 ± 7.9 min; p ≤ 0.00 l). The absolute accuracy of SpHb was 0.0 ± 0.8 g/dL and trend accuracy yielded a coefficient of determination of 0.93. Adding SpHb monitoring to standard of care blood management resulted in decreased blood utilization in high blood loss neurosurgery, while facilitating earlier transfusions.

	Standard Care Group (n=61)	SpHb Group (n=45)	*p*-Value
Baseline Hb (g/dL)	11.8 ± 1.6	11.6 ± 0.8	NS
Patients transfused, %	49	44	NS
Pretransfusion Hb (g/dL)	8.3 ± 1.2	8.6 ± 1.2	NS
Hb increase after transfusion (g/dL)	2.6 ± 1.2	1.8 ± 0.9	**<0.05**
RBC transfusions per subject, units	1.9 ± 2.3	1.0 ± 1.5	**<0.001**
RBC transfusions per subject receiving a transfusion, units	3.9 ± 1.7	2.3 ± 1.5	**<0.01**
Transfused patients receiving >3 RBC units, %	73	32	**<0.01**
Time to transfusion after need established (min)	50.2 ± 7.8	9.2 ± 0.7	**<0.001**

Masimo-supported Study

Award winning Publication, Study or Presentation.

41 The Value of Continuous Noninvasive Hemoglobin Monitoring in Intraoperative Blood Transfusion Practice During Abdominal Cancer Surgery

Kamal AM, Elramely MA, Abd Elhaq MM. *Open J Anesth.* 2016;13-19.

Introduction

Patients undergoing major oncological surgery may suffer from severe bleeding. Sometimes, it is difficult to anesthesiologist to take decision about timing of administration blood products to such patients. The aim of this study is to evaluate the use of continuous noninvasive hemoglobin monitoring as a guide for blood transfusion practice.

Methods

One hundred patients undergoing elective abdominal cancer surgeries were randomly allocated into two groups, Group I (n = 50): laboratory Hb was obtained at baseline (immediate preoperative), intraoperative (when to suggest transfusion triggering value) and immediate postoperative. Group II (n = 50): The probe of Masimo for SpHb monitoring was applied immediately after induction of anesthesia at the index finger. Laboratory Hb was obtained at baseline (immediate preoperative), intraoperative (when to suggest transfusion triggering value) and immediate postoperative.

Results

A number of transfused units of RBC were significantly lower in SpHb group than in control group (p value < 0.05), and a number of saved RBC units were significantly higher in SpHb group than in control group (p value < 0.001). The correlation between Lab Hb and SpHb was highly significant between baseline Lab Hb and baseline SpHb ($r = 0.698$, $p < 0.001$). Similarly, Lab Hb before transfusion showed a significant correlation between SpHb before transfusion ($r = 0.710$, $p < 0.001$). On the contrary, there was a non-significant correlation between Lab Hb after transfusion and SpHb after transfusion ($r = 0.045$, $p > 0.05$).

Conclusions

SpHb monitoring had clinically acceptable absolute and trend accuracy. SpHb monitoring altered transfusion decision making and resulted in decreased RBC utilization and decreased RBC costs while facilitating earlier transfusions when indicated.

Transfusion Data

	Group I	Group II	P
Blood loss (ml)	1.750 ± 655	1.690 ± 825	0.28
Transfused patients	30 (60%)	32 (64%)	0.12
Patients with blood loss exceeded 15%	15 (30%)	17 (34%)	0.31
No of transfused units	3.97 ± 1.64	2.42 ± 1.38	0.02
No of saved units	0.37 ± 0.55	1.55 ± 0.90	<0.001

02: Pulse CO-Oximetry – Total Hemoglobin (SpHb)

42 Economic Analysis of the Reduction of Blood Transfusions during Surgical Procedures While Continuous Hemoglobin Monitoring Is Used

Ribed-Sánchez B, González-Gaya C, Varea-Díaz S, Corbacho-Fabregat C, Pérez-Oteyza J, Belda-Iniesta C. *Sensors*. 2018 Apr 27;18(5).

Background

Two million transfusions are performed in Spain every year. These come at a high economic price for the health system, increasing the morbidity and mortality rates. The way of obtaining the hemoglobin concentration value is via invasive and intermittent methods, the results of which take time to obtain. The drawbacks of this method mean that some transfusions are unnecessary. New continuous noninvasive hemoglobin measurement technology can save unnecessary transfusions.

Methods

A prospective study was carried out with a historical control of two homogeneous groups. The control group used the traditional hemoglobin measurement methodology. The experimental group used the new continuous hemoglobin measurement technology. The difference was analyzed by comparing the transfused units of the groups. The economic savings was calculated by multiplying the cost of a transfusion by the difference in units, taking into account measurement costs.

Results

The percentage of patients needing a transfusion decreased by 7.4%, and the number of transfused units per patient by 12.56%. Economic savings per patient were €20.59. At the national level, savings were estimated to be 13,500 transfusions (€1.736 million).

Conclusions

Constant monitoring of the hemoglobin level significantly reduces the need for blood transfusions. By using this new measurement technology, health care facilities can significantly reduce costs and improve care quality.

Transfusion Results

Group Features	Total Patients (No.)	Transfusions (No.)	Transfusions (%)	Units of Blood (No.)	Units per Patient (No.)
Control Group	**115**	**56**	**48.7**	**152**	**1.322**
Women	*77*	*37*	*48.05*	*124*	*1.61*
Men	*38*	*19*	*50*	*28*	*0.74*
Experimental Group	**122**	**55**	**45.1**	**141**	**1.156**
Women	*69*	*30*	*43.5*	*103*	*1.49*
Men	*53*	*25*	*47.2*	*38*	*0.72*

43 Continuous Noninvasive Hemoglobin Monitoring Estimates Timing for Detecting Anemia Better Than Clinicians: A Randomized Controlled Trial.

Tang B, Yu X, Xu L, Zhu A, Zhang Y, Huang Y. *BMC Anesthesiol*. 2019 May 17;19(1):80. doi: 10.1186/s12871-019-0755-1.

Background

Hemoglobin measurement is important for transfusion decision-making. Pulse CO-Oximetry provides real-time continuous hemoglobin (SpHb) monitoring. The triage role of SpHb trends based on hemoglobin measurements was investigated.

Methods

In this diagnostic randomized controlled trial, 69 patients undergoing spine or cytoreductive surgery were randomly enrolled into SpHb-monitoring and standard-care groups. Diagnostic blood samples were drawn for CO-oximetry Hb (CoOxHb) when the SpHb decreased by 1 g/dl or at the clinician's discretion in the standard-care group. The positive predictive value (PPV) was defined as the ability to detect a decrease in CoOxHb > 1 g/dl or a CoOxHb < 10 g/dl; the PPVs were compared using Fisher's exact test. The SpHb and trend accuracies were calculated. The transfusion units and postoperative hemoglobin levels were compared.

Results

The PPV of a decrease in CoOxHb > 1 g/dl was 93.3% in the SpHb group vs 54.5% without SpHb monitoring (p = 0.002). The PPV of CoOxHb < 10 g/dl was 86.7% vs. 50.0% for these groups (p = 0.015). The CoOxHb was never < 7 g/dl with SpHb monitoring. Sixty SpHb-CoOxHb data pairs and 28 delta pairs (ΔSpHb-ΔCoOxHb) were collected. The bias, precision and limits of agreement were - 0.29, 1.03 and - 2.30 to 1.72 g/dl, respectively. When ΔSpHb and ΔCoOxHb were > 1 g/dl, the concordance rate for changes in hemoglobin reached 100%. The delta pairs revealed a positive correlation [ΔSpHb = 0.49 * ΔCoOxHb - 0.13; r = 0.69, 95% confidence interval (0.53, 0.82)]. No significant differences were found in the transfusion volume or postoperative anemia state.

Conclusions

The SpHb trend tracked changes in hemoglobin satisfactorily during surgery and more accurately estimated the appropriate timing for invasive hemoglobin measurements than the clinicians.

02: Pulse CO-Oximetry – Total Hemoglobin (SpHb)

44 Trending and Accuracy of Noninvasive Hemoglobin Monitoring in Pediatric Perioperative Patients

Patino M, Schultz L, Hossain M, Moeller J, Mahmoud M, Gunter J, Kurth CD. *Anesth Analg*. 2014 Oct;119(4):920-5.

Background

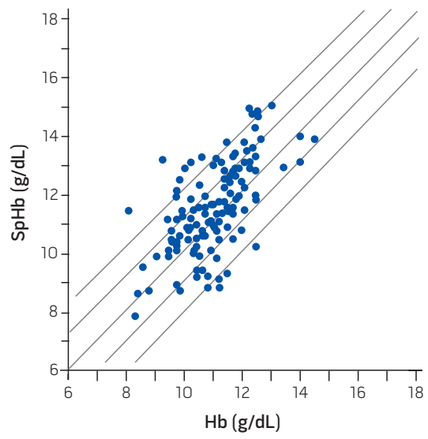
Rainbow Pulse CO-Oximetry technology (Masimo Corporation, Irvine, CA) provides continuous and noninvasive measurement of arterial hemoglobin concentration (SpHb). We assessed the trending and accuracy of SpHb by this innovative monitoring compared with Hb concentration obtained with conventional laboratory techniques (Hb) in children undergoing surgical procedures with potential for substantial blood loss.

Methods

Hb concentrations were recorded from Pulse CO-Oximetry and a conventional hematology analyzer. Regression analysis and 4-quadrant plot were used to evaluate the trending for changes in SpHb and Hb measurements (ΔSpHb and ΔHb). Bias, precision, and limits of agreement of SpHb and of in vivo adjusted SpHb (SpHb - first bias to HB) compared with Hb were calculated.

Results

One hundred fifty-eight SpHb-Hb data pairs and 105 delta pairs (ΔSpHb and ΔHb) from 46 patients aged 2 months to 17 years with Hb ranging from 16.7 to 7.9 g/dL were collected. To evaluate trending, the delta pairs (ΔSpHb and ΔHb) were plotted, which revealed a positive correlation (ΔSpHb = 0.022 + 0.76 ΔHb) with correlation coefficient r = 0.76, 95% CI [confidence interval] = 0.57-0.86. The bias and precision of SpHb to Hb and in vivo adjusted SpHb were 0.4 ± 1.3 g/dL and 0.1 ± 1.2 g/dL, respectively; the limits of agreement were -2.0 to 3.2 g/dL before in vivo adjustment and -2.4 to 2.2 g/dL after in vivo adjustment (P value = 0.04). The mean percent bias (from the reference Hb concentration) decreased from 4.1% ± 11.9% to 0.7% ± 11.3% (P value = 0.01). No drift in bias over time was observed during the study procedure. Of patient demographic and physiological factors tested for correlation with the SpHb, only perfusion index at sensor site showed a weak correlation.



Conclusions

The accuracy of SpHb in children with normal Hb and mild anemia is similar to that previously reported in adults and is independent of patient demographic and physiological states except for a weak correlation with perfusion index. The trending of SpHb and Hb in children with normal Hb and mild anemia showed a positive correlation. Further studies are necessary in children with moderate and severe anemia.

Masimo-supported Study

45

M

Accuracy of a Continuous Noninvasive Hemoglobin Monitor in Intensive Care Unit Patients

Frasca D, Dahyot-Fizelier C, Catherine K, Levrat Q, Debaene B, Mimoz O. *Crit Care Med*. 2011;39(10):2277-82.

Objective

To determine whether noninvasive hemoglobin measurement by pulse CO-Oximetry could provide clinically acceptable absolute and trend accuracy in critically ill patients, compared to other invasive methods of hemoglobin assessment available at bedside and the gold standard, the laboratory analyzer.

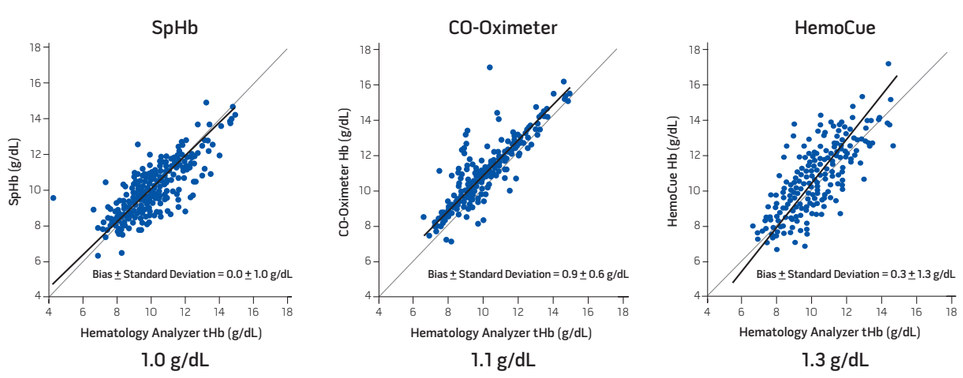
Methods

Design: Prospective study. **Setting:** Surgical intensive care unit of a university teaching hospital. **Patients:** Sixty-two patients continuously monitored with pulse CO-Oximetry (Masimo Radical-7). **Interventions:** None.

Results

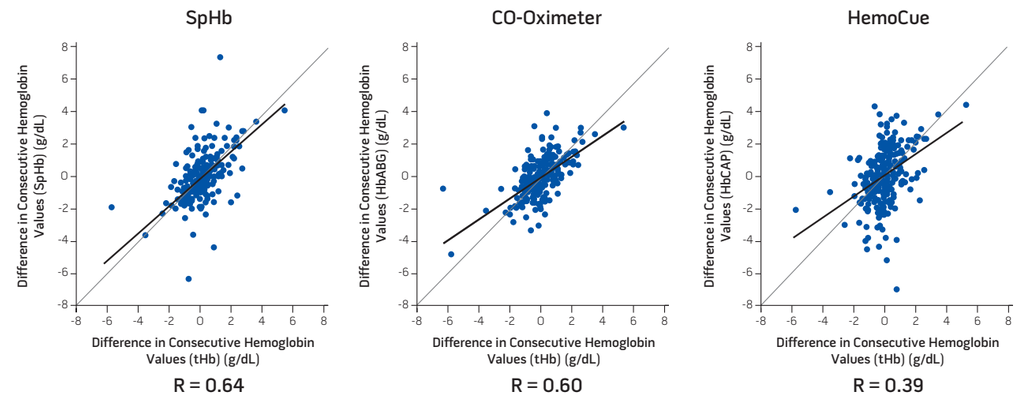
Four hundred seventy-one blood samples were analyzed by a point-of-care device (HemoCue 301), a satellite lab CO-oximeter (Siemens RapidPoint 405), and a laboratory hematology analyzer (Sysmex XT-2000i), which was considered the reference device. Hemoglobin values reported from the invasive methods were compared to the values reported by the pulseCO-oximeter at the time of blood draw. When the case-to-case variation was assessed, the bias and limits of agreement were 0.0 ± 1.0 g/dL for the pulse CO-oximeter, 0.3 ± 1.3 g/dL for the point-of-care device, and 0.9 ± 0.6 g/dL for the satellite lab CO-oximeter compared to the reference method. Pulse CO-Oximetry showed similar trend accuracy as satellite lab CO-Oximetry, whereas the point-of-care device did not appear to follow the trend of the laboratory analyzer as well as the other test devices.

Trend of Hemoglobin Change in Consecutive Measurement from Test Devices from a Laboratory Hematology Analyzer



M Masimo-supported Study

Agreement of Hemoglobin Values from Test Devices to Values from a Laboratory Hematology Analyzer



Conclusion

When compared to laboratory reference values, hemoglobin measurement with pulse CO-Oximetry has absolute accuracy and trending accuracy similar to widely used, invasive methods of hemoglobin measurement at bedside. Hemoglobin measurement with pulse CO-Oximetry has the additional advantages of providing continuous measurements, noninvasively, which may facilitate hemoglobin monitoring in the intensive care unit.

46 Continuous and Noninvasive Hemoglobin Monitoring During Complex Spine Surgery

Berkow L, Rotolo S, Mirski E. *Anesth. Analg*. 2011;113(6):1396-402.

Background

Monitoring hemoglobin levels in the operating room currently requires repeated blood draws, several steps, and a variable time delay to receive results. Consequently, blood transfusion management decisions may be delayed or made before hemoglobin results become available. The ability to measure hemoglobin continuously and noninvasively may enable a more rapid assessment of a patient's condition and more appropriate blood management. A new technology, Pulse CO-Oximetry, provides a continuous, noninvasive estimate of hemoglobin concentration (SpHb) from a sensor placed on the finger. We evaluated the accuracy of SpHb compared with laboratory CO-Oximetry measurements of total hemoglobin (tHb) during complex spine procedures in patients at high risk for blood loss.

Methods

Patients eligible for the study were undergoing complex spine surgery with planned invasive arterial or central venous monitoring and hourly blood draws for hemoglobin measurement. During each surgery, blood samples were obtained hourly (or more often if clinically indicated) and analyzed by the central laboratory with CO-Oximetry, a standard method of hemoglobin measurement in many hospitals. The tHb measurements were compared with SpHb obtained at the time of the blood draw.

Results

Twenty-nine patients were included in the study. The tHb values ranged from 6.9 to 13.9 g/dL, and the SpHb values ranged from 6.9 to 13.4 g/dL. A total of 186 data pairs (tHb/SpHb) were analyzed; after removal of SpHb readings with low signal quality, the bias (defined as the difference between SpHb and tHb) and precision (defined as 1 SD of the bias) were −0.1 g/dL ± 1.0 g/dL for the remaining 130 data pairs. Bland-Altman analyses showed good agreement of SpHb to tHb values over the range of values; limits of agreement were −2.0 to 1.8 g/dL. The absolute bias and precision were 0.8 ± 0.6 g/dL.

Conclusion

Continuous, noninvasive hemoglobin measurement via Pulse CO-Oximetry demonstrated clinically acceptable accuracy of hemoglobin measurement within 1.5 g/dL compared with a standard laboratory reference device when used during complex spine surgery. This technology may provide more timely information on hemoglobin status than intermittent blood sample analysis and thus has the potential to improve blood management during surgery.

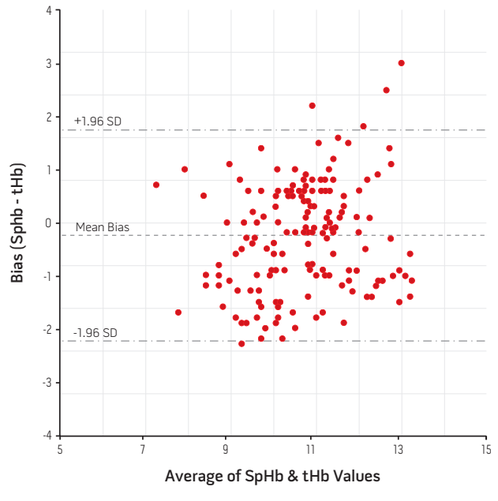


Figure 1: Bland-Altman plot for SpHb and total hemoglobin (tHb) measurements (n=186).

Masimo-supported Study

47 Continuous Noninvasive Hemoglobin Measurement is Useful in Patients Undergoing Double-Jaw Surgery

Kim SH, Choi JM, Kim HJ, Choi SS, Choi IC. *J Oral Maxillofac Surg*. 2014 Mar 28. S0278-2391(14)00324-3.

Purpose

Continuous measurement of hemoglobin by pulse CO-oximetry (SpHb; Masimo Radical 7 device, Masimo Corp, Irvine, CA) may be helpful during double-jaw surgery when massive hemorrhage is anticipated. Given the possible influence of low blood pressure on the detection of hemoglobin levels, the agreement of the SpHb was evaluated in patients undergoing orthognathic surgery when using hypotensive anesthesia.

Materials and Methods

Patients who underwent elective Le Fort I osteotomy and bilateral sagittal split ramus osteotomy (BSSO) were enrolled in this observational prospective cohort study. SpHb was compared with time-matched arterial total hemoglobin (tHb) before incision, at Le Fort I osteotomy, at BSSO, and at skin closure. The correlation between simultaneous SpHb and tHb measurement pairs was evaluated. Agreement was assessed by a comparison of SpHb with tHb using the intraclass correlation coefficient (ICC) and the Bland-Altman plot.

Results

The average age of 51 patients was 23 ± 5 years and 32 patients were male. The correlations of SpHb and tHb measurements were 0.72, 0.85, 0.89, and 0.78 before incision, at Le Fort I osteotomy, at BSSO, and at closure, respectively. Bland-Altman analysis for SpHb and tHb showed respective bias values of 0.12, 0.07, -0.09, and -0.90 g/dL. ICC values between SpHb and tHb were 0.82, 0.90, 0.91, and 0.87, respectively.

Statistical Analysis of Laboratory tHb, SpHb, MAP, Heart Rate, and Dose of Nicardipine Administered at Each Defined Time Point

	Before Incision	At Le Fort I Osteotomy	At BSSO	At Closure
tHb (g/dL)	12.6 ± 1.2	11.5 ± 1.3*	10.2 ± 1.4*†	10.0 ± 1.2*†¥
SpHb (g/dL)	12.7 ± 1.6	11.6 ± 1.8*	10.1 ± 2.0*†	9.1 ± 1.3*†¥

*P < .05 compared with before incision.
†P < .05 compared with at Le Fort I osteotomy.
¥P < .05 compared with at BSSO.

Conclusion

Conclusions Continuous monitoring of hemoglobin may help to determine the appropriate time to perform an invasive measurement of hemoglobin in patients who undergo double-jaw surgery.

48 Validation of Continuous and Noninvasive Hemoglobin Monitoring by Pulse CO-Oximetry in Japanese Surgical Patients

Isosu T, Obara S, Hosono A, Ohashi S, Nakano Y, Imaizumi T, Mogami M, Murakawa M. *J Clin Monit Comput*. 2013 Feb;27(1):55-60.

Introduction

We evaluated the accuracy of noninvasive and continuous total hemoglobin (SpHb) monitoring with the Radical-7 Pulse CO-Oximeter in Japanese surgical patients before and after an in vivo adjustment of the first SpHb value to match the first reference value from a satellite laboratory CO-Oximeter.

Methods

Twenty patients undergoing surgical procedures with general anesthesia were monitored with Pulse CO-Oximetry for SpHb. Laboratory CO-Oximeter values (tHb) were compared to SpHb at the time of the blood draws. Bias, precision, limits of agreement, and correlation coefficient of SpHb compared to tHb were calculated before and after SpHb values were adjusted by subtracting the difference between the first SpHb and tHb value from all subsequent SpHb values. Trending of SpHb to tHb and the effect of perfusion index (PI) on the agreement of SpHb to tHb were also analyzed.

Results

Ninety-two tHb values were compared to the SpHb. Bias ±1 SD was 0.2 ± 1.5 g/dL before in vivo adjustment and -0.7 ± 1.0 g/dL after in vivo adjustment. Bland-Altman analysis showed limits of agreement of -2.8 to 3.1 g/dL before in vivo adjustment and -2.8 to 1.4 g/dL after in vivo adjustment. The correlation coefficient was 0.76 prior to in vivo adjustment and 0.87 after in vivo adjustment. In patients with adequate perfusion (PI ≥1.4), the correlation coefficient was 0.89.

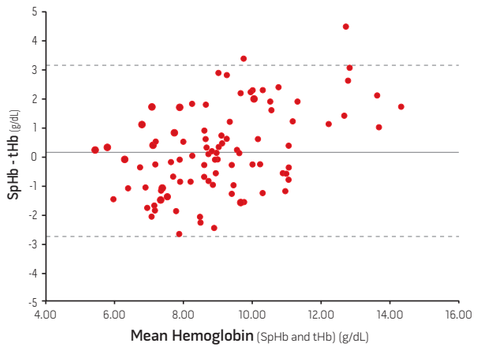


Figure 1: Bland-Altman plots for SpHb compared to tHb before in vivo adjustment.

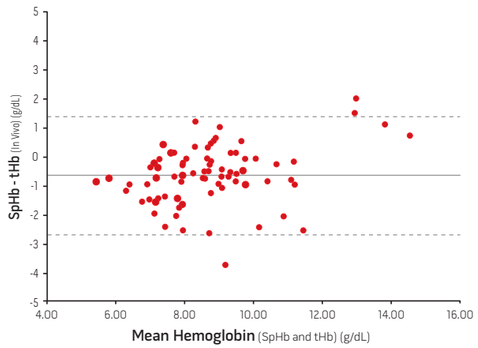


Figure 2: Bland-Altman plots for SpHb compared to tHb after in vivo adjustment.

Conclusion

In vivo adjustment of SpHb significantly improved the accuracy in our cohort of Japanese surgical patients. The strongest correlation between SpHb and tHb values was observed in patients with adequate peripheral perfusion, suggesting that low perfusion may affect the accuracy of SpHb monitoring.

03: rainbow Acoustic Monitoring

49

M

Accuracy of Respiratory Rate Monitoring Using a Noninvasive Acoustic Method After General Anaesthesia

Mimoz O, Benard T, Gaucher A, Frasca D, Debaene B. *Br J Anaesth*. 2012;108(5):872-5.

Background

Respiratory rate should be monitored continuously in the postanaesthesia care unit (PACU) to avoid any delay in the detection of respiratory depression. Capnometry is the standard of care but in extubated patients requires a nasal cannula or a face mask that may be poorly tolerated or can be dislodged, leading to errors in data acquisition and false alarms. The value of a new non-invasive acoustic monitor in this setting has not been fully investigated.

Methods

Adult patients admitted to the PACU after general anesthesia were included. After tracheal extubation, an adhesive sensor with an integrated acoustic transducer (RRa™) was placed on the patient's throat and connected to its monitor while the patient breathed through a face mask with a carbon dioxide sampling port (Capnomask™) connected to a capnometer. Both the acoustic monitor and the capnometer were connected to a computer to record a pair of data per second for up to 60 min.
Capnomask is not an Oridion product.

Results

Fifty-two patients, mean (range) age 54 (22-84) yr and BMI 26 (19-39) kg m(-2), were studied. Compared with capnometry, the bias and limits of agreement of the acoustic method were 0 (-1.4-1.4) bpm. The acoustic sensor was well tolerated while the face mask was removed by 8 patients, leading to study discontinuation in 2 patients.

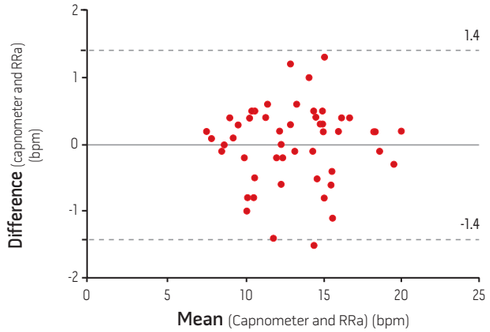


Figure 1: Bland-Altman plot of respiration rate by capnometry vs acoustic monitoring (RRa).

Event (n)	$EtCO_2$	RRa
Speaking (15)	11	4
Moving (7)	6	1
Coughing (5)	5	0
Repeated Swallowing (2)	0	2
Mask Removal (8)	8	--
Sensor Repositioning (13)	--	13

Figure 2: Events affecting the accuracy of respiration rate measurement of the 2 devices.

Conclusion

In extubated patients, continuous assessment of respiration rate with an acoustic monitor correlated well with capnometry.

M Masimo-supported Study

50 The Accuracy, Precision and Reliability of Measuring Ventilatory Rate and Detecting Ventilatory Pause by rainbow Acoustic Monitoring and Capnometry

Ramsay MAE, Usman M, Lagow E, Mendoza M, Untalan E, De Vol, E. *Anesth Analg.* 2013 Jul;117(1):69-75.

Background

Current methods for monitoring ventilatory rate have limitations including poor accuracy and precision and low patient tolerance. In this study, we evaluated a new acoustic ventilatory rate monitoring technology for accuracy, precision, reliability, and the ability to detect pauses in ventilation, relative to capnometry and a reference method in postsurgical patients.

Methods

Adult patients presenting to the postanesthesia care unit were connected to a Pulse CO-Oximeter with acoustic monitoring technology (Rad-87, version 7804, Masimo, Irvine, CA) through an adhesive bioacoustic sensor (RAS-125, rev C) applied to the neck. Each subject also wore a nasal cannula connected to a bedside capnometer (Capnostream20, version 4.5, Oridion, Needham, MA). The acoustic monitor and capnometer were connected to a computer for continuous acoustic and expiratory carbon dioxide waveform recordings. Recordings were retrospectively analyzed by a trained technician in a setting that allowed for the simultaneous viewing of both waveforms while listening to the breathing sounds from the acoustic signal to determine inspiration and expiration reference markers within the ventilatory cycle without using the acoustic monitor- or capnometer-calculated ventilatory rate. This allowed the automatic calculation of a reference ventilatory rate for each device through a software program (TagEditor, Masimo). Accuracy (relative to the respective reference) and precision of each device were estimated and compared with each other. Sensitivity for detection of pauses in ventilation, defined as no inspiration or expiration activity in the reference ventilatory cycle for ≥30 seconds, was also determined. The devices were also evaluated for their reliability, i.e., the percentage of the time when each displayed a value and did not drop a measurement.

Results

Thirty-three adults (73% female) with age of 45 ± 14 years and weight 117 ± 42 kg were enrolled. A total of 3712 minutes of monitoring time (average 112 minutes per subject) were analyzed across the 2 devices, reference ventilatory rates ranged from 1.9 to 49.1 bpm. Acoustic monitoring showed significantly greater accuracy (P = 0.0056) and precision (p = 0.0024) for respiratory rate as compared with capnometry. On average, both devices displayed data over 97% of the monitored time. The (0.95, 0.95) lower tolerance limits for the acoustic monitor and capnometer were 94% and 84%, respectively. Acoustic monitoring was marginally more sensitive (P = 0.0461) to pauses in ventilation (81% vs 62%) in 21 apneic events.

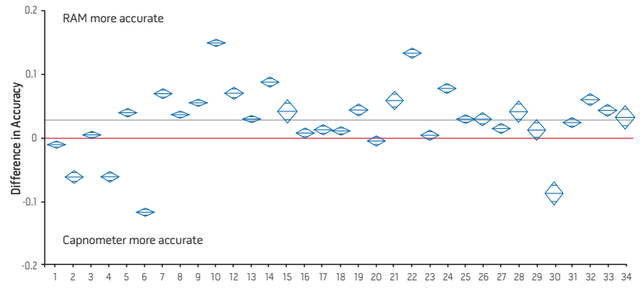


Figure 1: Difference in accuracy between two devices for each of 33 patients.

Conclusion

In this study of a population of postsurgical patients, the acoustic monitor and capnometer both reliably monitored ventilatory rate. The acoustic monitor was statistically more accurate and more precise than the capnometer, but differences in performance were modest. It is not known whether the observed differences are clinically significant. The acoustic monitor was more sensitive to detecting pauses in ventilation. Acoustic monitoring may provide an effective and convenient means of monitoring ventilatory rate in postsurgical patients.

Masimo-supported Study

51 Comparison of Postoperative Respiratory Monitoring by Acoustic and Transthoracic Impedance Technologies in Pediatric Patients at Risk of Respiratory Depression

Patino M, Kalin M, Griffin A, Minhajuddin A, Ding L, Williams T, Ishman S, Mahmoud M, Kurth CD, Szmuk P. *Anesth Analg*. 2017 Apr 24.

Background

In children, postoperative respiratory rate (RR) monitoring by transthoracic impedance (TI), capnography, and manual counting has limitations. The rainbow acoustic monitor (RAM) measures continuous RR noninvasively by a different methodology. Our primary aim was to compare the degree of agreement and accuracy of RR measurements as determined by RAM and TI to that of manual counting. Secondary aims include tolerance and analysis of alarm events.

Methods

Sixty-two children (2-16 years old) were admitted after tonsillectomy or receiving postoperative patient/parental-controlled analgesia. RR was measured at regular intervals by RAM, TI, and manual count. Each TI or RAM alarm resulted in a clinical evaluation to categorize as a true or false alarm. To assess accuracy and degree of agreement of RR measured by RAM or TI compared with manual counting, a Bland-Altman analysis was utilized showing the average difference and the limits of agreement. Sensitivity and specificity of RR alarms by TI and RAM are presented.

Results

Fifty-eight post-tonsillectomy children and 4 patient/parental-controlled analgesia users aged 6.5 ± 3.4 years and weighting 35.3 ± 22.7 kg (body mass index percentile 76.6 ± 30.8) were included. The average monitoring time per patient was 15.9 ± 4.8 hours. RAM was tolerated 87% of the total monitoring time. The manual RR count was significantly different from TI (P = .007) with an average difference ± SD of 1.39 ± 10.6 but were not significantly different from RAM (P = .81) with an average difference ± SD of 0.17 ± 6.8. The proportion of time when RR measurements differed by ≥4 breaths was 22% by TI and was 11% by RAM. Overall, 276 alarms were detected (mean alarms/patient = 4.5). The mean number of alarms per patient were 1.58 ± 2.49 and 2.87 ± 4.32 for RAM and TI, respectively. The mean number of false alarms was 0.18 ± 0.71 for RAM and 1.00 ± 2.78 for TI. The RAM was found to have 46.6% sensitivity (95% confidence interval [CI], 0.29-0.64), 95.9% specificity (95% CI, 0.90-1.00), 88.9% positive predictive value (95% CI, 0.73-1.00), and 72.1% negative predictive value (95% CI, 0.61-0.84), whereas the TI monitor had 68.5% sensitivity (95% CI, 0.53-0.84), 72.0% specificity (95% CI, 0.60-0.84), 59.0% positive (95% CI, 0.44-0.74), and 79.5% negative predictive value (95% CI, 0.69-0.90).

Conclusion

In children at risk of postoperative respiratory depression, RR assessment by RAM was not different to manual counting. RAM was well tolerated, had a lower incidence of false alarms, and had better specificity and positive predictive value than TI. Rigorous evaluation of the negative predictive value is essential to determine the role of postoperative respiratory monitoring with RAM.

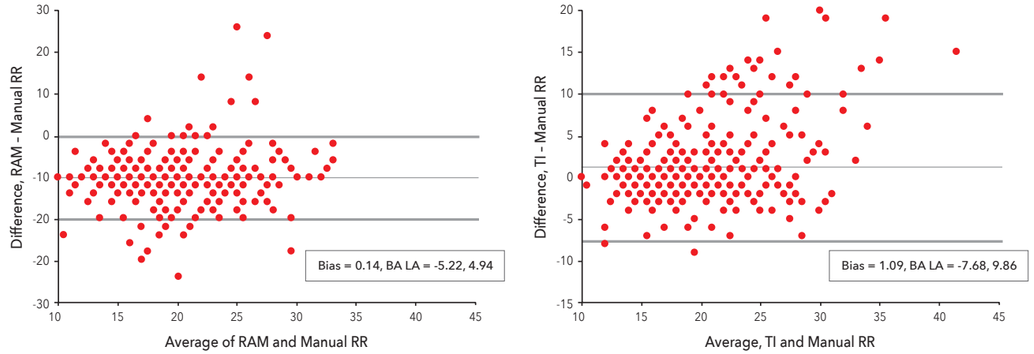


Figure 1: Bland–Altman plots for agreement between RAM and TI RR with manual counts RR. RAM indicates rainbow acoustic monitor; RR, respiratory rates; TI, transthoracic impedance.

Masimo-supported Study

52 Comparison of Acoustic and Impedance Methods with Mask Capnometry to Assess Respiration Rate in Obese Patients Recovering from General Anaesthesia

Frasca D, Geraud L, Charriere JM, Debaene B, Mimoz O. *Anaesthesia*. 2015 Jan;70(1):26-31.

Background

Respiratory depression, a potentially serious complication after general anaesthesia, can be detected promptly by close monitoring of both oxygen saturation and respiratory rate. Obese patients have morphological changes that may impair the reliability of monitoring devices.

Methods

In this study, respiration rate was simultaneously recorded every second for up to 60 min using a computer in 30 adult obese patients (body mass index ≥ 35 kg.m(-2)), by three methods: acoustic; thoracic impedance; and capnometry via a facemask (Capnomask, reference method).

Of the 99,771 data triplets collected, only 85,520 (86%) were included; 12,021 (84%) were not studied due to failure of capnometry and 2240 (16%) due to failure of the acoustic method.

Results

Compared with capnometry, bias was similar using both the acoustic method and impedance (-0.3 bpm vs. -0.6 bpm, respectively, p = 0.09), but limits of agreement were narrower for the acoustic method (±3.5 bpm vs. ±5.3 bpm, respectively, p = 0.0008). The proportion of respiration rate values obtained with the acoustic method and impedance that differed by at least 10% or 20% for more than 15 s were 11% vs. 23% and 2% vs. 6%, respectively (p = 0.0009 for both comparisons). The acoustic sensor was well tolerated, while the facemask was pulled off on several occasions by four (13%) agitated patients.

Conclusion

In obese patients requiring close monitoring of respiration rate, the acoustic method may be more precise than thoracic impedance and better tolerated than capnometry with a facemask.

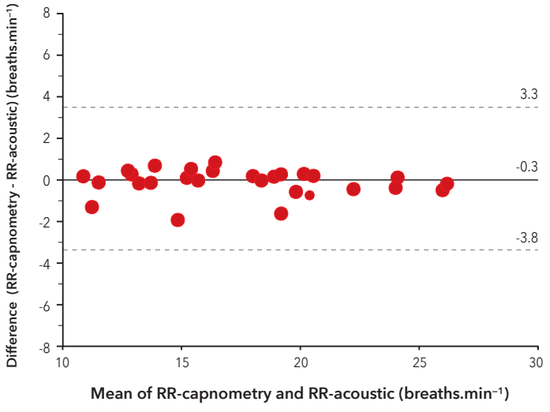


Figure 1: Graphic representation according to the Bland and Altman method of bias (solid line) and limits of aggreement (dotted lines) between the respiratory rate obtained by capnometry (RR-Capnometry) using a facemask and the acoustic device (RR-acoustic). Each circle represents one patient measurement, and the size of the circle is proportional to the number of measurements.

Masimo-supported Study

53 Comparison of Acoustic Respiration Rate, Impedance Pneumography and Capnometry Monitors for Respiration Rate Accuracy and Apnea Detection during GI Endoscopy Anesthesia

Goudra BG, Penugonda LC, Speck RM, Sinha AC. *Open J Anesthesiol*. 2013; 3:74-79.

Study Objective

To assess the accuracy of respiration rate measurements and the ability to detect apnea by capnometry, impedance pneumography and a new method, acoustic respiration rate monitoring, in anesthetized patients undergoing gastrointestinal endoscopy procedures.

Methods

Design: Prospective observational study. **Setting:** Endoscopy procedures laboratory.

Patients: 98 patients scheduled for upper gastrointestinal endoscopy with propofol-based anesthesia.

Interventions: Patients were monitored for respiration rate with acoustic respiration rate monitoring, capnometry and impedance pneumography and values were compared to the manual counting of breaths by observation of chest wall movements. Additionally, when any respiration rate monitor indicated a cessation of breathing for 30 seconds or greater, the presumed apnea was confirmed by direct observation of the patient for absence of chest wall movements.

Measurements and Main Results

Bias and precision for respiration rate measurement was 0 ± 1.0 bpm for acoustic monitoring, 4.8 ± 15.1 bpm for capnometry and 0.4 ± 5.9 bpm for impedance pneumography. Sensitivity and specificity for detection of apnea was 73% and 93% for acoustic monitoring, 73% and 12% for capnometry and 45% and 93% for impedance pneumography.

A	Clinical Observation	RRa Monitoring	Capnometry	Impedance Pneumography
True Positives	11	8	8	5
True Negatives	113	105	13	105
False Positives	*na*	8	100	8
False Negatives	*na*	3	3	6
Sensitivity = TP/[TN+FN] [CI], %	*na*	73 [39–93.9]	73 [39–93.9]	45 [16.8–76.6]
Specificity = TN/[TN+FP] [CI], %	*na*	93 [86.5–96.9]	12 [6.3–18.9]	93 [86.5–96.9]

Conclusion

Acoustic respiration rate monitoring was found to be accurate for assessment of respiration rate and to have similar or better sensitivity and specificity for detection of apnea compared to capnometry and impedance pneumography in the setting of upper GI endoscopy.

54 Accuracy of Acoustic Respiration Rate Monitoring in Pediatric Patients

M

Patino M, Redford DT, Quigley TW, Mahmoud M, Kurth CD, Szmuk P. *Paediatr Anaesth*. 2013 Sep 3.

Background

rainbow acoustic monitoring (RRa) utilizes acoustic technology to continuously and noninvasively determine respiratory rate from an adhesive sensor located on the neck.

Objective

We sought to validate the accuracy of RRa, by comparing it to capnography, impedance pneumography, and to a reference method of counting breaths in postsurgical children.

Methods

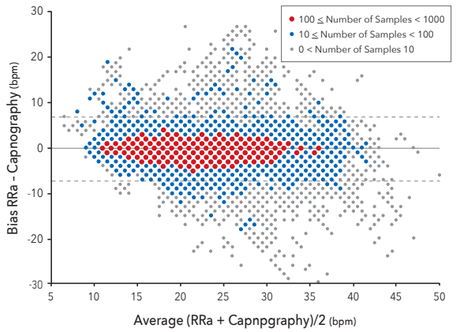
Continuous respiration rate data were recorded from RRa and capnography. In a subset of patients, intermittent respiration rate from thoracic impedance pneumography was also recorded. The reference method, counted respiratory rate by the retrospective analysis of the RRa, and capnographic waveforms while listening to recorded breath sounds were used to compare respiration rate of both capnography and RRa. Bias, precision, and limits of agreement of RRa compared with capnography and RRa and capnography compared with the reference method were calculated. Tolerance and reliability to the acoustic sensor and nasal cannula were also assessed.

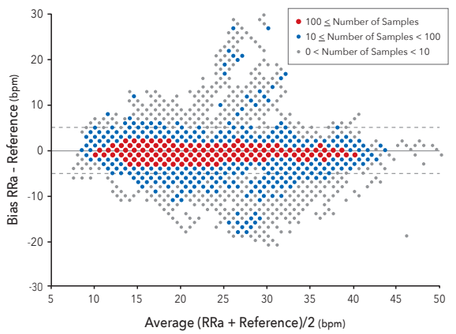
Results

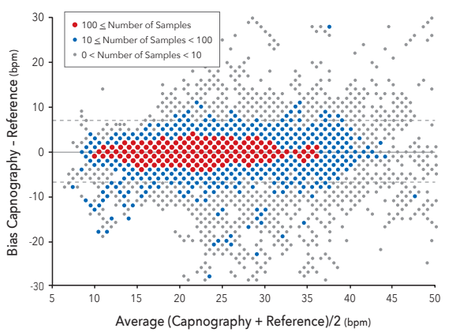
Thirty-nine of 40 patients (97.5%) demonstrated good tolerance of the acoustic sensor, whereas 25 of 40 patients (62.5%) demonstrated good tolerance of the nasal cannula. Intermittent thoracic impedance produced erroneous respiratory rates (>50 b.min-1 from the other methods) on 47% of occasions. The bias ± SD and limits of agreement were -0.30 ± 3.5 b.min-1 and -7.3 to 6.6 b.min-1 for RRa compared with capnography; -0.1 ± 2.5 b.min-1 and -5.0 to 5.0 b.min-1 for RRa compared with the reference method; and 0.2 ± 3.4 b.min-1 and -6.8 to 6.7 b.min-1 for capnography compared with the reference method.

Conclusions

When compared to nasal capnography, RRa showed good agreement and similar accuracy and precision but was better tolerated in postsurgical pediatric patients.







M Masimo-supported Study

55 Accuracy and Tolerance of a Novel Bioacoustic Respiratory Sensor in Pediatric Patients

Macknet MR, Kimball-Jones PL, Applegate RL, Martin RD, Allard MW. *Anesthesiology*. 2007;107:A84 (abstract).

Introduction

Monitoring respiration of spontaneously breathing patients is a concern in the operating room, postanesthesia care unit (PACU), and on general care wards. Present technology has focused on capnometry attached to the patient's airway via a nasal cannula as the best method of providing this monitoring.[1] There are multiple problems with this method of monitoring respiration, including cannula dislodgement or occlusion leading to inaccurate data or complete loss of monitoring.[2] A novel bioacoustic sensor for monitoring respiration has been developed. We evaluated the accuracy of the new bioacoustic sensor compared to the capnometer cannula system in pediatric postoperative patients.

Methods

Following institutional IRB approval and informed consent, 6 pediatric patients admitted to the PACU were monitored in the standard fashion. In addition, a nasal cannula was placed, secured with tape, and connected to a BCI capnometer (SIMS, Waukesha, WI). An adhesive bioacoustic sensor connected to a breathing frequency monitor prototype (Masimo Corp, Irvine, CA) was applied to the patient's neck just lateral to the cricoid cartilage. Both the capnometer and the bioacoustic monitor were connected to a computer for continuous data recording. The accuracy of the new bioacoustic sensor and the capnometer were compared to a reference respiratory rate from a manual scoring system. Bias, precision, and A_{RMS} were calculated in the usual fashion, as either bioacoustic – reference or capnometer – reference.

Results

All data are expressed as mean ± standard deviation. Six patients (age = 11 ± 6.3 years, weight = 23.8 ± 89.4 kg) were enrolled to date in the accuracy trial. Respiratory rate varied 3 to 35 bpm during this time. The resultant bias, precision, and A_{RMS} for the capnometer was -1.17, 3.74, and 3.92 bpm respectively. The bias, precision, and A_{RMS} for the bioacoustic sensor was -0.03, 3.49, and 3.49 bpm respectively.

	Bias ± SD (bpm)	A_{RMS} (bpm)
Acoustic Monitoring (RRa)	-0.03 ± 3.49	3.49
Capnometry	-1.17 ± 3.74	3.92

Discussion

The new prototype bioacoustic respiratory sensor demonstrates accuracy for respiratory rate monitoring as good as capnometry in this population of pediatric patients in the PACU. This device offers multiple benefits over existing devices and has a potential to improve monitoring in a general care setting. In clinical settings where continuous and reliable monitoring of spontaneous respiration is important, the new bioacoustic sensor provides equivalent accuracy; however, it does not require a cannula system. This should lead to significantly more reliable monitoring of respiration rate.

References

[1] *Pediatrics*. 2006;117;1170-1178. [2] *Medical and Biological Engineering and Computing*. 2003;41;377-383.

56

Performance of Masimo rainbow Acoustic Monitoring for Tracking Changing Respiratory Rates Under Laryngeal Mask Airway General Anesthesia for Surgical Procedures in the Operating Room: A Prospective Observational Study

Atkins JH, Mandel JE., *Anesth Analg*. 2014 Jul 14.

Background

Accurate monitoring of respiratory rate may be useful for the early detection of patient deterioration. Monitoring of respiratory rate in the operating room under general anesthesia by spirometry is technically straightforward and demonstrates high fidelity. Accurate measurement of the respiratory rate of an unattended patient outside the operating room is fraught with challenges. Monitors such as capnometry and thoracic impedance pneumography have significant drawbacks. Respiratory acoustic monitoring (RRa™) is a new have significant drawbacks. Respiratory acoustic monitoring (RRa™) is a new provide accurate respiratory rates in patients recovering from anesthesia, but the performance of this RRa-enabled monitor under conditions of major respiratory rate variation has not been evaluated.

Methods

We enrolled 53 patients undergoing urologic procedures in the operating room under general anesthesia with a laryngeal mask airway, spontaneous ventilation, and no muscle relaxation in an observational study. Respiratory signals (RRa and in-circuit pneumotachograph) were stored for later analysis. Artifacts were excluded based on visual inspection of the raw respiratory waveforms. Instantaneous respiratory rates were obtained from the pneumotachograph signal using the Hilbert-Huang Transform. Instantaneous rate estimates (IREs) were compared with RRa by 3 methods. First, the mean delay between IREs and RRa was determined. Second, precision was obtained by Bland-Altman analysis for repeated measures. Third, for all disparities in rates exceeding 4 breaths per minute (bpm), the probability of persistent error was determined as a function of time, with 95% confidence intervals estimated by bootstrap analysis.

Results

RESULTS: Data were collected from 53 patients. Three patients were excluded due to missing data. There were no adverse events related to RRa monitoring. RRa demonstrated a median delay of 45 seconds (interquartile range 20 seconds) to detect a 1- bpm change in IREs. Bland-Altman revealed 95% limits of agreement of -2.1 to 2.2 bpm across the range of 7 to 48 bpm. Disparities in respiratory rate >4 bpm between the 2 methods did not persist beyond 160 seconds, and 90% of these differences resolved within 33 seconds (95% confidence interval 23-48 seconds).

Masimo-supported Study

03: rainbow® Acoustic Monitoring® – Acoustic Respiration Rate (RRa)

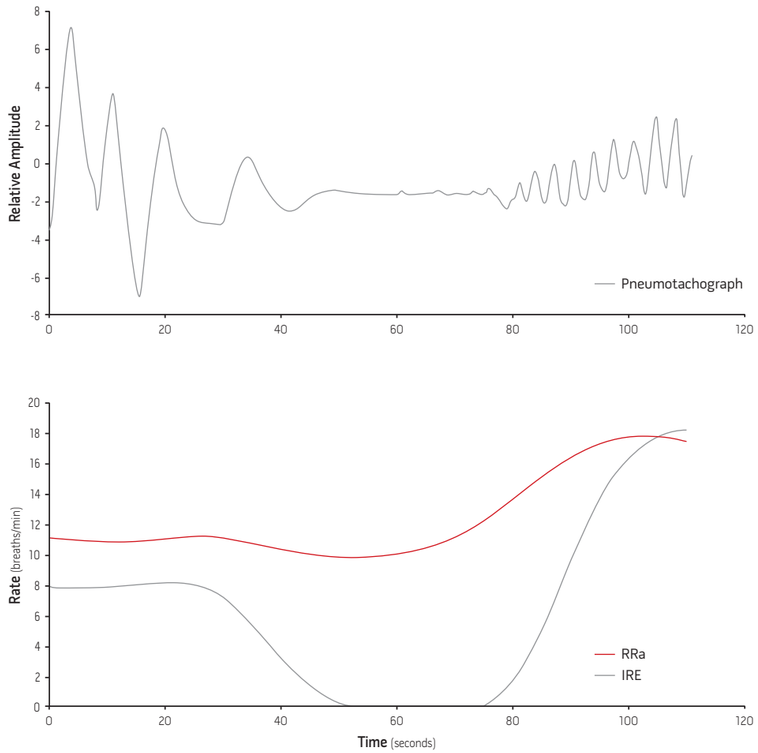


Figure 1 & 2: Upper panel, Pneumotachograph signal. Lower panel, instantaneous rate estimates (IREs) rate (red) and respiratory acoustic monitoring (RRa™) rate (blue) during a respiratory pause induced by discontinuing pressure support ventilation. Respiratory rates are filtered with zero-phase low-pass filter with cutoff frequency of 0.025 Hz. Masimo RRa will display the most recently acquired respiratory rate until the pause detection algorithm is triggered after approximately 30 seconds.

Conclusions

The data demonstrate that, under conditions of general anesthesia with a laryngeal mask airway and spontaneous ventilation, the RRa rapidly detects changes in respiratory rate, demonstrates minimal bias, and when errors in rate occur, these do not persist. The utility of this monitoring technology in detecting rate changes in unattended patients will require further study.

04: Brain Monitoring

57

M

Titration of Delivery and Recovery from Propofol, Alfentanil, and Nitrous Oxide Anesthesia

Drover DR, Lemmens HJ, Pierce ET, Plourde G, Loyd G, Ornstein E, Prichep LS, Chabot RJ, Gugino L. *Anesthesiology* 2002; 97:82–9.

Background

The Patient State Index (PSi) uses derived quantitative electroencephalogram features in a multivariate algorithm that varies as a function of hypnotic state. Data are recorded from two anterior, one midline central, and one midline posterior scalp locations. PSi has been demonstrated to have a significant relation to level of hypnosis during intravenous propofol, inhalation, and nitrous oxide–narcotic anesthesia. This multisite study evaluated the utility of PSi monitoring as an adjunct to standard anesthetic practice for guiding the delivery of propofol and alfentanil to accelerate emergence from anesthesia.

Methods

Three hundred six patients were enrolled in this multicenter prospective randomized clinical study. Using continuous monitoring throughout the period of propofol–alfentanil–nitrous oxide anesthesia delivery, PSi guidance was compared with use of standard practice guidelines (both before [historic controls] and after exposure to the PSA 4000 monitor [Physiometrix, Inc., N. Billerica, MA; standard practice controls]). Anesthesia was always administered with the aim of providing hemodynamic stability, with rapid recovery.

Results

No significant differences were found for demographic variables or for site. The PSi group received significantly less propofol than the standard practice control group (11.9 μg kg-1 min-1; $P < 0.01$) and historic control group (18.2 μg kg-1 min-1; $P < 0.001$). Verbal response time, emergence time, extubation time, and eligibility for operating room discharge time were all significantly shorter for the PSi group compared with the historic control (3.3–3.8 min; $P < 0.001$) and standard practice control (1.4 –1.5 min; $P < 0.05$ or $P < 0.01$) groups. No significant differences in the number of unwanted somatic events or hemodynamic instability and no incidences of reported awareness were found.

Conclusions

Patient State Index–directed titration of propofol delivery resulted in faster emergence and recovery from propofol–alfentanil–nitrous oxide anesthesia, with modest decrease in the amount of propofol delivered, without increasing the number of unwanted events.

	Historic Controls (HC) Mean/(±95%)	Standard Practice Controls (SPC) Mean/(±95%)	PSI Monitored Mean/(±95%)
Verbal response time (min)	10.4 (8.7–12.1)	8.5 (7.5–9.5)	7.1§‖ (6.3–7.9)
Emergence time (min)	9.9 (8.2–11.6)	7.9 (6.9–8.8)	6.5§‖ (5.7–7.3)
Extubation time (min)	11.2 (9.1–13.2)	8.9* (7.9–9.8)	7.4§‖ (6.5–8.2)
Eligible for OR discharge (min)	13.9 (11.3–16.6)	11.0 (9.8–12.2)	9.0§# (8.0–10.0)
Eligible for PACU discharge (min)	59.3 (43.9–74.8)	56.7 (49.4–63.9)	51.7 (44.0–59.4)
Total alfentanil ($\mu g \cdot kg^{-1} \cdot min^{-1}$)	0.65 (0.57–0.74)	0.69 (0.65–0.74)	0.69 (0.65–0.74)
Normalized propofol infusion rates ($\mu g \cdot kg^{-1} \cdot min^{-1}$)	140.7 (128.2–153.2)	134.4 (128.2–140.6)	122.5‡# (116.3–128.7)

Table 1: Efficacy and Recovery End Points across Patient Groups

* $P < 0.05$ for SPC *versus* HC. †, ‡, § $P < 0.05$, 0.01, or 0.001 for Patient State Index (PSi) monitored *versus* HC. ‖, # $P < 0.05$ or 0.01 for PSi *versus* SPC.
OR = operating room; PACU = postanesthesia care unit

M Masimo-supported Study

58 Is The Patient State Analyzer With The Psarray2 A Cost-Effective Alternative To The Bispectral Index Monitor During The Perioperative Period?

White PF, Tang J, Ma H, Wender RH, Sloninsky A, Kariger R. *Anesth Analg*. 2004 Nov;99(5):1429-35.

Background

New disposable electrodes, the PSArray and XP sensor, have been developed for the patient state analyzer (PSA) and the bispectral index (BIS) monitors, respectively. We designed this clinical study to compare the sensitivity and specificity of the patient state index (PSi) with the BIS during the perioperative period when the new electrode sensors were used.

Methods

Twenty-two consenting patients scheduled for elective laparoscopic procedures were enrolled in this prospective study. The elapsed time to apply electrodes and obtain a baseline index value was recorded, as were the comparative PSi and BIS values at specific time intervals during the induction, maintenance, and emergence periods in patients who were administered a standardized general anesthetic. In addition, the changes in these indices were recorded after a bolus dose of propofol (20 mg IV) or a 2% increase or decrease in the inspired concentration of desflurane during the maintenance period.

Results

The total elapsed time to obtain an index value was similar with both devices (66 ± 32 s versus 72 ± 41 s for the PSA and BIS, respectively). By using logistic regression models, both the BIS and PSi were found to be equally effective as predictors of unconsciousness (i.e., failure to respond to verbal stimuli). The PSi also correlated with the BIS during both the induction of (R = 0.85) and the emergence from (R = 0.74) general anesthesia. The area under the receiver operating characteristic curve for detection of consciousness also indicated a similar performance with the PSi (0.98 ± 0.05) and the BIS (0.97 ± 0.05). During the maintenance period, the PSi values tended to be lower than the BIS value; however, the responses to changes in propofol and desflurane were similar. Finally, the PSi (versus BIS) values showed less interference from the electrocautery unit during the operation (31% versus 73%, respectively). Although the list price of the PSArray(2) disposable electrode strip (USD $24.95) was higher than that of the BIS XP sensor (USD $17.50), the average sale price (USD $14.95) was identical for both electrode systems.

Conclusion

Therefore, we conclude that the PSA monitor with the PSArray(2) is a cost-effective alternative to the BIS monitor with the XP sensor for evaluating consciousness during the induction of and emergence from general anesthesia, as well as for titrating propofol and desflurane during the maintenance period.

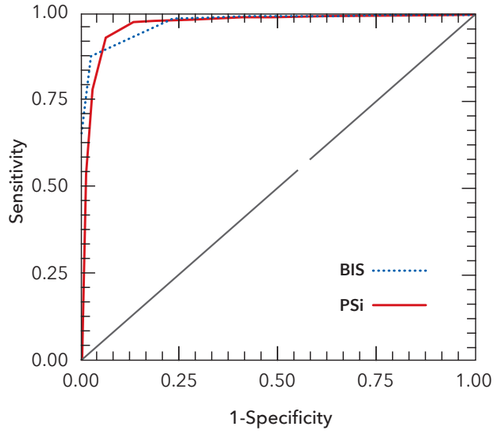


Figure 1: Receiver operating characteristics curves for discrete threshold values of the bispectral index (BIS) and the patient state index (PSi). The area under PSi curve was similar to the area under the BIS curve (0.98 ± 0.05 versus 0.97 ± 0.05, respectively).

59 Effects of Sevoflurane and Propofol on Frontal Electroencephalogram Power and Coherence

Akeju O, Westover MB, Pavone KJ, Sampson AL, Hartnack KE, Brown EN, Purdon PL. *Anesthesiology*. 2014 Nov;121(5):990-8.

Background

The neural mechanisms of anesthetic vapors have not been studied in depth. However, modeling and experimental studies on the intravenous anesthetic propofol indicate that potentiation of γ-aminobutyric acid receptors leads to a state of thalamocortical synchrony, observed as coherent frontal alpha oscillations, associated with unconsciousness. Sevoflurane, an ether derivative, also potentiates γ-aminobutyric acid receptors. However, in humans, sevoflurane-induced coherent frontal alpha oscillations have not been well detailed.

Methods

To study the electroencephalogram dynamics induced by sevoflurane, the authors identified age- and sex-matched patients in which sevoflurane (n = 30) or propofol (n = 30) was used as the sole agent for maintenance of general anesthesia during routine surgery. The authors compared the electroencephalogram signatures of sevoflurane with that of propofol using time-varying spectral and coherence methods.

Results

Sevoflurane general anesthesia is characterized by alpha oscillations with maximum power and coherence at approximately 10 Hz, (mean ± SD; peak power, 4.3 ± 3.5 dB; peak coherence, 0.73 ± 0.1). These alpha oscillations are similar to those observed during propofol general anesthesia, which also has maximum power and coherence at approximately 10 Hz (peak power, 2.1 ± 4.3 dB; peak coherence, 0.71 ± 0.1). However, sevoflurane also exhibited a distinct theta coherence signature (peak frequency, 4.9 ± 0.6 Hz; peak coherence, 0.58 ± 0.1). Slow oscillations were observed in both cases, with no significant difference in power or coherence.

Conclusion

The study results indicate that sevoflurane, like propofol, induces coherent frontal alpha oscillations and slow oscillations in humans to sustain the anesthesia-induced unconscious state. These results suggest a shared molecular and systems-level mechanism for the unconscious state induced by these drugs.

60 Intraoperative Effect of Dexmedetomidine Infusion During Living Donor Liver Transplantation: A Randomized Control Trial

Sayed E, Yassen KA. *Saudi J Anaesth*. 2016 Jul-Sep;10(3):288-94.

Background

Dexmedetomidine hydrochloride (Dex) is a useful adjuvant for general anesthesia. The aim was to evaluate the effects of Dex infusion during living donors liver transplantation (LDLT) on the general anesthetic requirements, hemodynamics, oxygen consumption (VO_2), and CO_2 production (VCO_2).

Materials and Methods

Forty LDLT recipients were allocated randomly to receive either Dex (0.2- 0.7 μg/kg/h) or placebo (control [C]). Patient state index (PSi), SedLine monitored anesthesia depth (25-50) with desflurane (Des) % and fentanyl altered accordingly. Transesophageal Doppler (TED), invasive mean arterial blood pressure (MAP) and heart rate (HR) were monitoring any Dex side effects and altering infusion rate accordingly; TED was used for fluid optimization. Metabolic gas monitoring (VO_2, VCO_2) and Des consumption were recorded.

Results

Dex reduced Des and fentanyl consumption versus C (120.0 ± 30.2 vs. 248.0 ± 38.8) ml, (440.0 ± 195.74 vs. 1300.0 ± 32) μg, respectively ($P < 0.01$). Dex was delivered for 11.35 ± 2.45 h with comparable HR, MAP, and TED variables versus C and with similar mean noradrenaline support (5.63 ± 2.44 vs. 5.83 ± 2.57 mg, $P = 0.81$). VO_2 was reduced with Dex vs. C during anhepatic, 30 min postreperfusion and end of surgery (193.2 ± 26.78 vs. 239 ± 14.93) (172.1 ± 28.14 vs. 202.7 ± 18.03) and (199.7 ± 26.63 vs. 283.8 ± 14.83) ml/min/m(2) respectively ($P < 0.01$). VCO_2 was also reduced with Dex versus C during the same periods (195.2 ± 46.41 vs. 216.7 ± 29.90, $P = 0.09$), (210.6 ± 60.71 vs. 253.9 ± 32.51, $P = 0.01$), and (158.7 ± 49.96 vs. 209.7 ± 16.78, $P < 0.01$), ml/min/m(2) respectively.

Conclusions

TED and PSi guided Dex infusion helped to reduce Des and fentanyl consumption as well as VO_2 and VCO_2 at a lower cost with no adverse effects on hemodynamics.

61 Absolute and Trend Accuracy of a New Regional Oximeter in Healthy Volunteers During Controlled Hypoxia

Redford D, Paidy S, Kashif F. *Anesth Analg*. 2014 Dec;119(6):1315-9.

Background

Traditional patient monitoring may not detect cerebral tissue hypoxia, and typical interventions may not improve tissue oxygenation. Therefore, monitoring cerebral tissue oxygen status with regional oximetry is being increasingly used by anesthesiologists and perfusionists during surgery. In this study, we evaluated absolute and trend accuracy of a new regional oximetry technology in healthy volunteers.

Methods

A near-infrared spectroscopy sensor connected to a regional oximetry system (O3, Masimo, Irvine, CA) was placed on the subject's forehead, to provide continuous measurement of regional oxygen saturation (rSO_2). Reference blood samples were taken from the radial artery and internal jugular bulb vein, at baseline and after a series of increasingly hypoxic states induced by altering the inspired oxygen concentration while maintaining normocapnic arterial carbon dioxide pressure ($PaCO_2$). Absolute and trend accuracy of the regional oximetry system was determined by comparing rSO_2 against reference cerebral oxygen saturation ($SavO_2$), that is calculated by combining arterial and venous saturations of oxygen in the blood samples.

Results

Twenty-seven subjects were enrolled. Bias (test method mean error), standard deviation of error, standard error of the mean, and root mean square accuracy (A_{RMS}) of rSO_2 compared to $SavO_2$ were 0.4%, 4.0%, 0.3%, and 4.0%, respectively. The limits of agreement were 8.4% (95% confidence interval, 7.6%-9.3%) to -7.6% (95% confidence interval, -8.4% to -6.7%). Trend accuracy analysis yielded a relative mean error of 0%, with a standard deviation of 2.1%, a standard error of 0.1%, and an A_{RMS} of 2.1%. Multiple regression analysis showed that age and skin color did not affect the bias (all $P > 0.1$).

Conclusions

Masimo O3 regional oximetry provided absolute root-mean-squared error of 4% and relative root-mean-squared error of 2.1% in healthy volunteers undergoing controlled hypoxia.

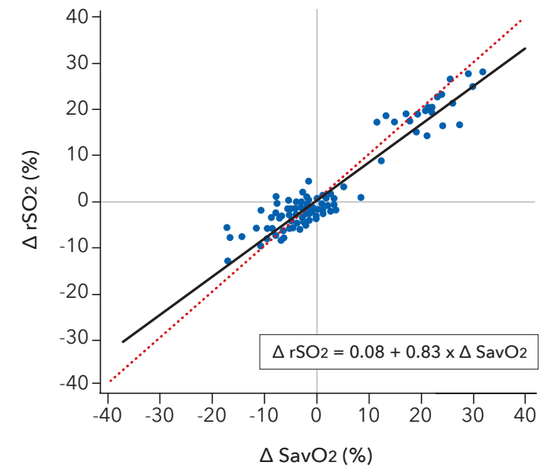


Figure 1: Mixed effect regression analysis for an assessment of trending performance of rSO_2: scatter plot of 179 paired measurements for sample-to-sample changes, $\Delta SaVO_2$, and ΔrSO_2. Also shown are the line of identity (red) and the trend line representing the regression equation (black).

Masimo-supported Study

62 Four-wavelength Near-infrared Peripheral Oximetry in Cardiac Surgery Patients: A Comparison Between EQUANOX and O3

Ferraris A, Jacquet-Lagrèze M, Fellahi JL. *J Clin Monit Comput*. 2017 May 2.

Background

Near-infrared spectroscopy (NIRS) is a continuous and noninvasive technology that measures regional tissue oxygen saturation (rSO_2). A new 4-wavelength generation of NIRS monitors is now available. We aimed to compare peripheral somatic rSO_2 values given by the 4-wavelength EQUANOX™ 7600 device (Nonin Medical Inc., Plymouth, Mn) and O3™ device (Masimo Corporation, Irvine, CA). Twenty adult patients scheduled for conventional elective cardiac surgery with cardiopulmonary bypass over a 4-month period were included after local Ethics Committee approval. For each patient, 2 NIRS sensors (EQUANOX and O3) were placed over the medial part of the forearm. Thirteen couples of measurements were performed at predefined intraoperative time points. We compared 260 couples of absolute intraoperative rSO_2 values. No significant difference was found between both monitors: EQUANOX median rSO_2 60% (95% CI 57-62) versus O3 median rSO_2 62% (95% CI 61-64), P = 0.103. Bias was 4.0% and limits of agreement were ±26.3%. Significant correlations were evidenced between EQUANOX and O3 rSO_2 absolute values: rho = 0.758 (95% CI 0.701-0.806), P < 0.0001, and rSO_2 percent maximum difference versus baseline: rho = 0.582 (95% CI 0.188-0.815), P = 0.007. While absolute values of rSO_2 given by both devices were equivalent and well correlated, the clinical agreement is probably not acceptable, meaning that EQUANOX and O3 are not interchangeable in routine practice.

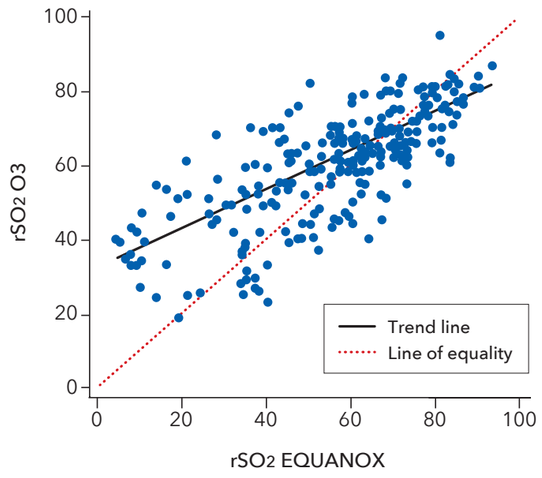


Figure 1: The relationship between absolute values of peripheral rSO_2 given by EQUANOX and O3 in 20 patients. N = 260 couples of measurements, rho = 0.758 (95% CI 0.701–0.806), P <0.001

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