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Pulse Oximetry

Pulse CO-Oximetry

rainbow Acoustic Monitoring®

Hemodynamic Monitoring

Brain Monitoring

Capnography

High-Flow Nasal Oxygen Therapy

For a full listing of available citations,
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Ⓜ Masimo-supported Study

16 "Motion-Resistant" Pulse Oximetry: A Comparison of New and Old Models
Barker SJ. *Anesth Analg*. 2002;95(4):967-72.

17 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.

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21 Differences in Pulse Oximetry Technology Can Affect Detection of Sleep-Disordered Breathing in Children
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Dale NM, Parshuram C, Tomlinson G, Shepherd S, Mohammed Ashir G, Bukar LM, Zlotkin S. *Acta Paediatr*. 2021 Jul;110(7):2249-2251.

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M **82** The Accuracy, Precision and Reliability of Measuring Ventilatory Rate and Detecting Ventilatory Pause by rainbow Acoustic Monitoring and Capnometry

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M **86** Comparison of Acoustic and Impedance Methods with Mask Capnometry to Assess Respiration Rate in Obese Patients Recovering from General Anaesthesia

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Atkins JH, Mandel JE., *Anesth Analg*. 2014 Dec;119(6):1307-14.

** 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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LiDCO

SedLine

Ⓜ Masimo-supported Study

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O3

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106 Patient Management Algorithm Combining Processed Electroencephalographic Monitoring With Cerebral and Somatic Near-infrared Spectroscopy: A Case Series

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NomoLine ISA

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Bräunlich J, Wirtz H. *Int J Chron Obstruct Pulmon Dis*. 2018 Nov 30;13:3895-3897

115 Nasal Highflow Improves Ventilation in Patients With COPD

Bräunlich J, Goldner F, Wirtz H. *Respir Physiol Neurobiol*. 2017 Aug;242:86-88.

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by Care Area and Patient Population

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Pleth Variability Index (continued)			
44	Feissel M et al., 2013	ER	Adults
45	Desbbe O et al., 2010	ICU	Adults
46	García-de-Acilu et al., 2021	ICU	Adults
47	Zimmermann et al., 2010	OR	Adults
48	Haas et al., 2012	OR	Adults
49	Demir et al., 2022	ED	Pediatrics
50	Tsuchiya M et al., 2010	OR	Adults
51	Desgranges F.P. et al., 2011	OR	Adults
52	Takeyama M et al., 2011	OR	Adults
Respiratory Rate from the Pleth (RRp)			
53	Dale et al., 2021	Children's Hospital	Pediatrics
54	Alwadhi et al., 2010	ED / OPD	Pediatrics
Patient SafetyNet			
55	McGrath et al., 2021	General Ward	Adults
56	McGrath et al., 2021	General Ward	Adults
57	Taenzer et al., 2010	Orthopedic Unit	Adults
58	Taenzer et al., 2012	Surgical and Medical units	Adults
59	McGrath et al., 2016	General Ward	Adults
60	Ishikawa et al., 2021	General Ward	Adults

02: Pulse CO-Oximetry

Total Hemoglobin (SpHb)			
61	Cros et al., 2019	OR / PACU / ICU	Adults
62	Applegate et al., 2019	OR	Adults
63	Merolle et al., 2020	Semi-Intensive Post-Surgery (SIPO) Ward	Adults
64	Ehrenfeld et al., 2014	OR	Adults
65	Ribed-Sánchez et al., 2018	OR	Adults
66	Nakamori et al., 2021	OR / ICU	Adults
67	Elsakka et al., 2017	OR / ICU	Adults
68	Awada et al., 2015	OR	Adults
69	Kamal et al., 2016	OR	Adults
70	Saracoglu et al., 2022	OR / ICU	Pediatrics
71	Clemmesen CG et al., 2019	OR	Adults
72	Tang et al., 2019	OR	Adults
73	Frasca et al., 2011	ICU	Adults
74	Patino et al., 2014	OR / In Vivo Adjustment	Pediatrics
75	Berkow et al., 2011	OR	Adults
76	Kim et al., 2014	OR	Adults
77	Isosu et al., 2013	OR / In Vivo Adjustment	Adults
Carboxyhemoglobin (SpCO)			
78	Eminoğlu et al., 2022	OR / PACU	Adults
Methemoglobin (SpMet)			
79	Conroy et al., 2016	Pediatric Ward	Pediatrics
80	Brandt et al., 2022	Plastic Surgery Clinic	Adults

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by Care Area and Patient Population

Number	First Author, Year	Care Area	Population
06: Capnography			
NomoLine ISA			
111	Hamdy et al., 2019	ICU	Adults
EMMA			
112	Hotta et al., 2020	NICU	Infants
07: High Flow Nasal Oxygen Therapy			
softFlow			
113	Bräunlich et al., 2019	Respiratory Ward	Adults
114	Bräunlich et al., 2018	Respiratory Ward	Adults
115	Bräunlich et al., 2017	Respiratory Ward	Adults

01: Pulse Oximetry

01

Racial Effects on Masimo Pulse Oximetry: A Laboratory Study

Barker SJ, Wilson WC. *J Clin Monit Comput*. 2023 Apr;37(2):567-574. doi: 10.1007/s10877-022-00927-w. Epub 2022 Nov 12.

Introduction

Recent publications have suggested that pulse oximeters exhibit reduced accuracy in dark-skinned patients during periods of hypoxemia. Masimo SET® (Signal Extraction Technology®) has been designed, calibrated, and validated using nearly equal numbers of dark and light skinned subjects, with the goal of eliminating differences between pulse oximetry saturation (SpO_2) and arterial oxygen saturation (SaO_2) values due to skin pigmentation. The accuracy concerns reported in dark-skinned patients led us to perform a retrospective analysis of healthy Black and White volunteers. Seventy-five subjects who self-identified as being racially Black or White underwent a desaturation protocol where SaO_2 values were decreased from 100 to 70%, while simultaneous SpO_2 values were recorded using Masimo RD SET® sensors. Statistical bias (mean difference) and precision (standard deviation of difference) were − 0.20 ± 1.40% for Black and − 0.05 ± 1.35% for White subjects. Plots of SpO_2 versus SaO_2 show no significant visible differences between races throughout the saturation range from 70 to 100%. Box plots grouped in 1% saturation bins, from 89−96%, and plotted against concomitant SaO_2 values, show that occult hypoxemia ($SaO_2 < 88\%$ when $SpO_2 = 92-96\%$) occurred in only 0.2% of White subject data pairs, but not in any Black subjects. There were no clinically significant differences in bias (mean difference of SpO_2-SaO_2) found between healthy Black and White subjects. Occult hypoxemia was rare and did not occur in Black subjects. Masimo RD SET® can be used with equal assurance in people with dark or light skin. These laboratory results were obtained in well-controlled experimental conditions in healthy volunteers—not reflecting actual clinical conditions/patients.

Fig. 1a

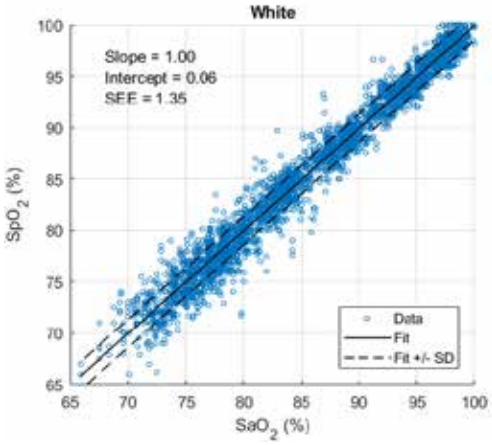


Fig. 1b

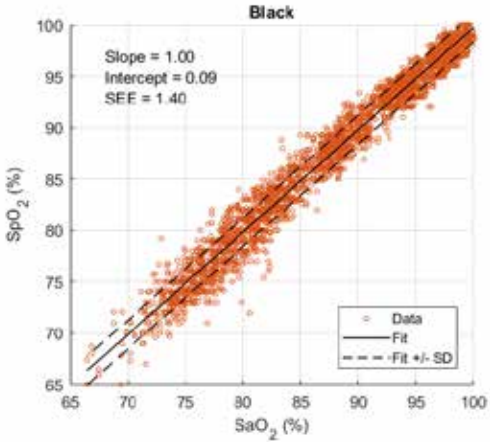


Figure 1. Scatter plot (SpO_2 versus SaO_2) along with performance metrics for White subjects (Fig. 1a) vs. Black subjects (Fig. 1b)

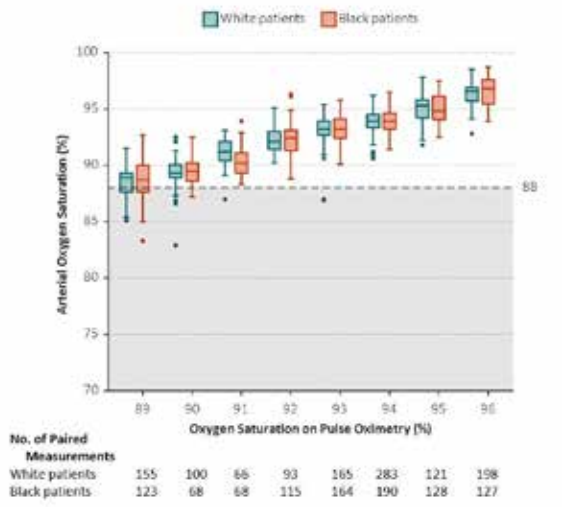


Figure 2. Box plot showing accuracy comparison for Black (salmon tint) and White (blue tint) ethnic groups binned by 1% saturation bins, from 89-96%. Shaded area of SaO_2%.

02 Prevention of Retinopathy of Prematurity in Preterm Infants through Changes in Clinical Practice and SpO2 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 SpO2 target was ≥93% and pulse oximetry technology was the same in both centres. In Period 2, guidelines for SpO2 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

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.

03 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

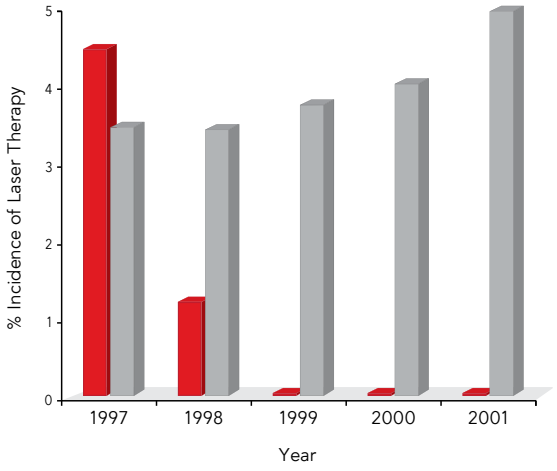
A wide variability in the incidence of severe retinopathy of prematurity (ROP) is reported by different centers. The altered regulation of vascular endothelial growth factor from repeated episodes of hyperoxia and hypoxia is an important factor in the pathogenesis of ROP. Strict management of O_2 delivery 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

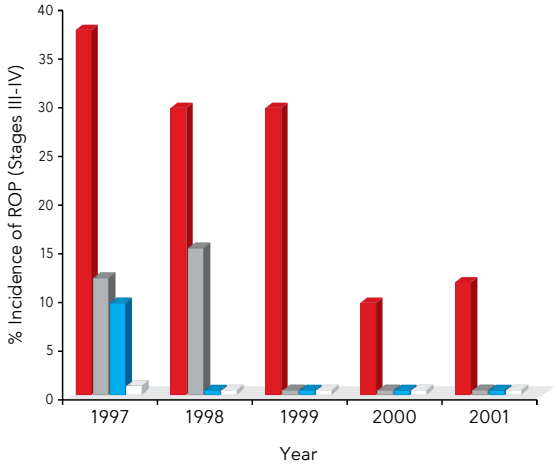
An oxygen management policy that included strict guidelines in the practices of increasing and weaning a fraction of inspired oxygen (FIO_2) and the monitoring of O_2 saturation parameters in the delivery room during in-house transport of infants to the NICU and throughout hospitalization was implemented 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.



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.



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 [study investigators] 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.

04 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 [investigators'] 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.

05 Avoiding Hyperoxemia During Neonatal Resuscitation: Time to Response of Different SpO2 Monitors

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

Aim

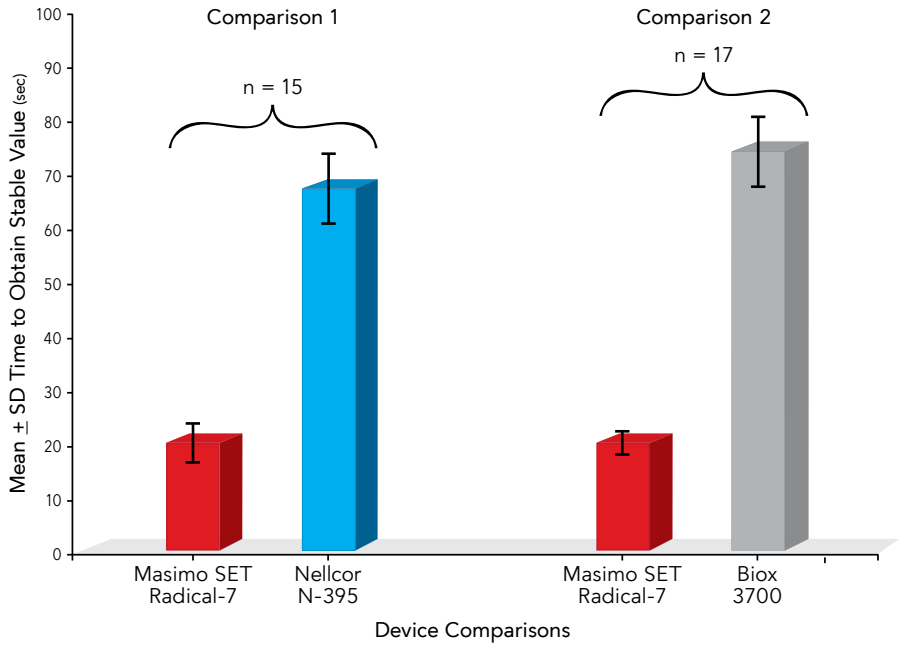
To assess the time to obtain reliable oxygen saturation readings by different pulse oximeters during neonatal resuscitation in the delivery room or NICU.

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 SpO2 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.

06 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 [study investigators] 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 [investigators] 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 [study investigators] made a data collection plan before recruitment. We [study investigators] then undertook a large, prospective, and multicentre screening study in which we [study investigators] 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 [study investigators] identified false-negative results by clinical follow-up and parents' feedback. We [study investigators] 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 [study investigators] 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.

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

	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)

07 First Day of Life Pulse Oximetry Screening to Detect Congenital Heart Defects

Meberg A, Brügmann-Pieper S, Due R Jr, Eskedal L, Fagerli I, Farstad T, Frøisland DH, Sannes CH, Johansen OJ, Keljalic J, Markestad T, Nygaard EA, Røsvik A, Silberg IE. *J Pediatr*. 2008 Jun;152(6):761-5.

Objective

To evaluate the efficacy of first day of life pulse oximetry screening to detect congenital heart defects (CHDs).

Study Design

We [investigators] performed a population-based prospective multicenter study of postductal (foot) arterial oxygen saturation (SpO_2) in apparently healthy newborns after transfer from the delivery suite to the nursery. SpO_2 < 95% led to further diagnostic evaluations. Of 57,959 live births, 50,008 (86%) were screened. In the screened population, 35 CHDs were [corrected] classified as critical (ductus dependent, cyanotic). CHDs were prospectively registered and diagnosed in 658/57,959 (1.1%) [corrected]

Results

Of the infants screened, 324 (0.6%) failed the test. Of these, 43 (13%) had CHDs (27 critical), and 134 (41%) had pulmonary diseases or other disorders. The remaining 147 infants (45%) were healthy with transitional circulation. The median age for babies with CHDs at failing the test was 6 hours (range, 1-21 hours). For identifying critical CHDs, the pulse oximetry screening had a sensitivity rate of 77.1% (95% CI, 59.4-89.0), specificity rate of 99.4% (95% CI, 99.3-99.5), and a false-positive rate of 0.6% (95% CI, 0.5-0.7).

Conclusion

Early pulse oximetry screening promotes early detection of critical CHDs and other potentially severe diseases. The sensitivity rate for detecting critical CHDs is high, and the false-positive rate is low.

	Pulse oximetry		Pulse oximetry + clinical examination	
	Critical CHDs	CHDs in total	Critical CHDs	CHDs in total
Number of patients with CHDs detected	27/35	43/434	31/35	363/434
Sensitivity rate, % (true-positive rate; 95% CI)	77.1 (59.4-89.0)	9.9 (7.3-13.2)	88.6 (72.3-96.3)	83.6 (79.7-86.9)
Specificity, % (95% CI)	99.4 (99.3-99.5)	99.4 (99.3-99.5)	99.4 (99.3-99.5)	99.9 (99.8-99.9)
Positive predictive value, % (95% CI)	8.3 (5.7-12.0)	13.3 (9.9-17.6)	9.6 (6.7-13.4)	83.6 (79.7-86.9)
Negative predictive value, % (95% CI)	99.98 (99.97-99.99)	99.2 (99.1-99.3)	99.99 (99.98-100)	99.86 (99.82-99.89)
False-positive rate, % (95% CI)	0.6 (0.5-0.7)	0.6 (0.5-0.6)	0.6 (0.5-0.7)	0.1 (0.1-0.2)

The accuracy of first day of life pulse oximetry screening (postductal SpO_2 < 95%) for detecting congenital heart defects in apparently healthy babies in the nursery (n = 50,008)

08 Perfusion Index and Pulse Oximetry Screening for Congenital Heart Defects

Schena F, Picciolli I, Agosti M, Zuppa AA, Zuccotti G, Parola L, Pomero G, Stival G, Markart M, Graziani S, Gagliardi L, Bellan C, La Placa S, Limoli G, Calzetti G, Guala A, Bonello E, Mosca F; Neonatal Cardiology Study Group of the Italian Society of Neonatology. *J Pediatr*. 2017 Apr;183:74-79.e1.

Objective

To evaluate the efficacy of combined pulse oximetry (POX) and perfusion index (PI) neonatal screening for severe congenital heart defects (sCHD) and assess different impacts of screening in tertiary and nontertiary hospitals.

Study Design

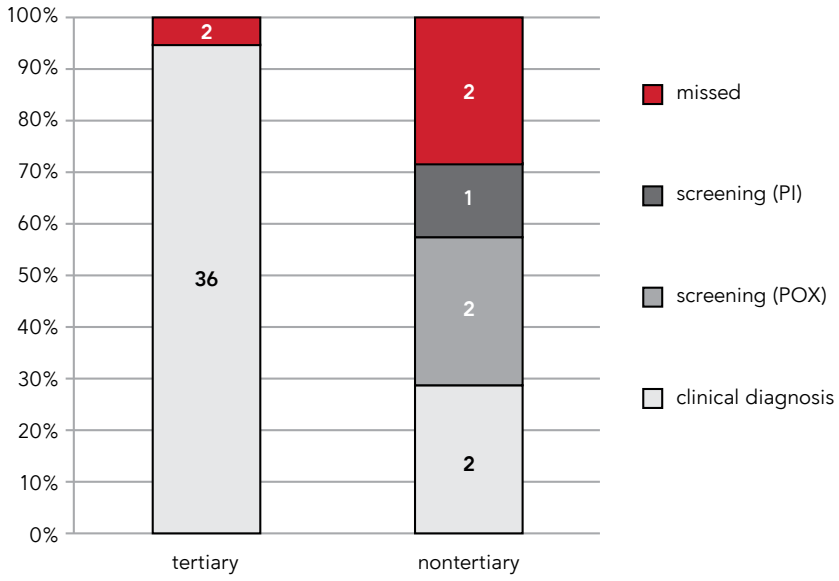
A multicenter, prospective study in 10 tertiary and 6 nontertiary maternity hospitals. A total of 42 169 asymptomatic newborns from among 50 244 neonates were screened; exclusion criteria were antenatal sCHD diagnosis, postnatal clinically suspected sCHD, and neonatal intensive care unit admission. Eligible infants underwent pre- and postductal POX and PI screening after routine discharge examination. Targeted sCHD were anatomically defined. Positivity was defined as postductal oxygen saturation (SpO_2) ≤95%, prepostductal SpO_2 gradient >3%, or PI <0.90. Confirmed positive cases underwent echocardiography for definitive diagnosis. Missed cases were identified by consulting clinical registries at 6 regional pediatric heart centers. Main outcomes were incidence of unexpected sCHD; proportion of undetected sCHD after discharge in tertiary and nontertiary hospitals; and specificity, sensitivity, positive predictive value, and negative predictive value of combined screening.

Results

One hundred forty-two sCHD were detected prenatally. Prevalence of unexpected sCHD was 1 in 1115 live births, similar in tertiary and nontertiary hospitals. Screening identified 3 sCHD (low SpO_2, 2; coarctation for low PI, 1). Four cases were missed. In tertiary hospitals, 95% of unsuspected sCHDs were identified clinically, whereas only 28% in nontertiary units; in nontertiary units PI-POX screening increased the detection rate to 71%.

Conclusion

PI-POX predischarge screening provided benefits in nontertiary units, where clinical recognition rate was low. PI can help identify coarctation cases missed by POX but requires further evaluation in populations with higher rates of missed cases.



Diagnostic modalities for prenatally undiagnosed sCHD in tertiary and nontertiary maternity units.

09 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 [study investigators] 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.

10 Post-implementation Review of Pulse Oximetry Screening of Well Newborns in an Australian Tertiary Maternity Hospital

Bhola K, Kluckow M, Evans N. *J Paediatr Child Health*. 2014 Nov;50(11):920-5.

Aim

Despite there being evidence that pulse oximetry screening is better than clinical examination alone in early detection of CHD, implementation has been slow. The aim of this paper was to evaluate the practice after its implementation into routine care at Royal Prince Alfred Hospital in 2008.

Methods

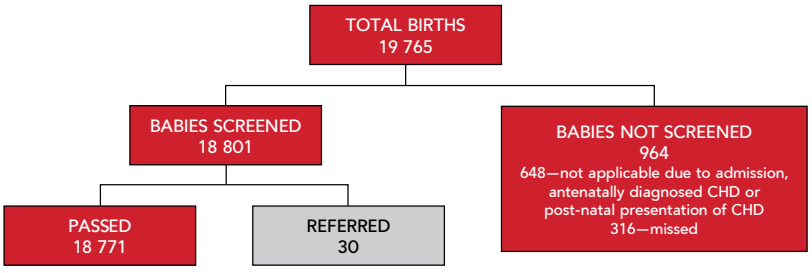
A single pulse oximetry measurement was incorporated in the routine discharge newborn examination or, with early discharge, as a part of the Midwife Discharge Support Programme. An oxygen saturation level greater than or equal to 95% was considered normal, and a level less than 95%, confirmed on a repeat measure, triggered a review and examination by a consultant neonatal paediatrician. The saturation levels were recorded in the hospital database. Ascertainment of major CHD requiring surgery in the first 12 months was performed by searching the cardiac surgery database of the Heart Centre for Children.

Results

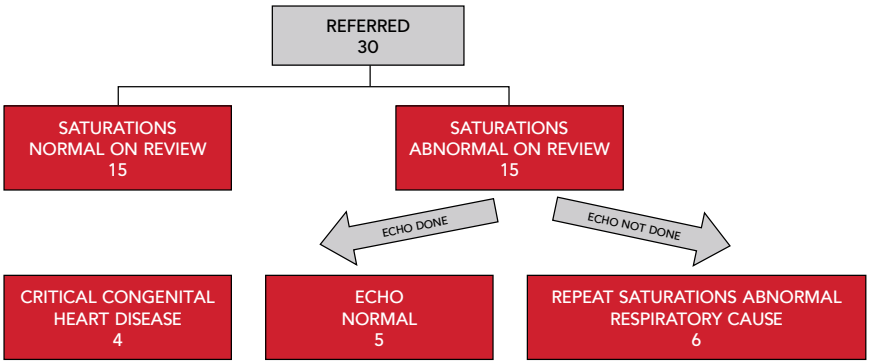
A total of 18,801 babies were screened over a 42-month period. Of these, four babies with major CHD were diagnosed prior to discharge with the main clinical alert resulting from routine pulse oximetry screening (true positive). Of the 11 cases with saturation <95% but no CHD (false positive cases), six had respiratory pathology. One baby with normal saturation level needed surgery in the first year for a large ventricular septal defect (false negative). The false positive rate of pulse oximetry screening for CHD was 0.13% with sensitivity 80%, specificity of 99.8%, a positive predictive value of 13.3% and a negative predictive value of 99.9%. Nine additional echocardiogram were required over 42 months.

Conclusion

These post-implementation data confirm that pulse oximetry screening increases early diagnosis of major CHD as well as other important pathology with a very low false positive rate and minimal requirement for extra echocardiograms. Pulse oximetry screening of apparently well newborns should become a standard of care.



Population screened by pulse oximetry at Royal Prince Alfred Hospital (RPAH).



Management of the cases that had a positive screen.

11 The Importance and Effectiveness of Cardiac Screening in Early Diagnosis of Critical Congenital Heart Diseases

Alan C., Korkmaz L. *Annals of Medical Research*. 2021;28(10), 1917–1921.

Aim

Cardiac screening test for early diagnosis of critical congenital heart disease (CCHD) is recommended by our [investigators'] ministry of health in newborns. We [study researchers] wanted to investigate the effectiveness of the pulse-oximetry screening test recommended by the ministry of health in our [investigators'] neonatal intensive care unit. Our [investigators'] study is planned to find an answer to this question regarding the subject matter.

Materials and Methods

Our [investigators'] study was planned retrospectively in cases followed up in our [investigators'] neonatal intensive care unit and obstetrics and gynecology clinic. Our [investigators'] study cases were accepted to the neonatal service of our [investigators'] hospital starting from 01/10/2015 in the 30-month period. Patients admitted from the neonatal and obstetrics / gynecology services were included in the study. Saturation measurements of these cases were made at the earliest 6th hour after birth. The test was considered positive, if saturation was <90 % in the right hand or the saturation was 90-94 % plus the right hand and any of the lower extremities saturation difference was greater than 3 % in three measurements performed at one hour intervals. Pulse-oximetry screening test was performed in all cases included in the study. SPSS 21.0 (Chicago, Illinois) was used for statistical analysis.

Results

A total of 12,504 cases were included in our [investigators'] study. Considering the exclusion criteria, some of our [investigators'] cases were excluded from the study, and CCHD was detected in 45 of the 12,223 cases accepted by ECHO examination. 36 of these 45 cases were suspected of CCHD with a physical examination and 41 with the pulse-oximetry screening test and were referred to the pediatric cardiology outpatient clinic. Pulse-oximetry screening test was positive in all 36 cases with CCHD determined by physical examination, but physical examination was found negative in 5 of 41 cases where pulse-oximetry screening test was positive. The 4 CCHD patients in the study could not be determined either by physical examination or by the pulse-oximetry screening test.

Conclusion

Physical examination alone does not have sufficient sensitivity and specificity. Pulse-oximetry screening test is more effective than physical examination in detecting neonatal cases with CCHD. Therefore, the appropriate combination of physical examination and pulse-oximetry screening test in the detection of CCHD cases may provide an advantage to physicians in early diagnosis.

Detection Methods of cases with CCHD

	TOF (n:5)	Ebstain (n:3)	PA (n:3)	HLHS (n:12)	IAA (n:9)	Critical AS (n:1)	TA (n:5)	TGA (n:7)
PE (+) Pulse-oximetry screening test (+)	3	3	3	9	7	1	5	5
PE (+) Pulse-oximetry screening test (-)	-	-	-	-	-	-	-	-
PE (-) Pulse-oximetry screening test (+)	1	-	-	1	1	-	-	2
PE (-) Pulse-oximetry screening test (-)	1	-	-	2	1	-	-	-
Cases with CCHD detected by ECHO	5	3	3	12	9	1	5	7
PE in cases with CCHD (+) (n:36/45)	3/5 (%60.0)	3/3 (%100)	3/3 (%100)	9/12 (%75.0)	7/9 (%77.7)	1/1 (%100)	5/5 (%100)	5/7 (%71.4)
Pulse-oximetry screening test in cases with CCHD (+) (n:41/45)	4/5 (%80.0)	3/3 (%100)	3/3 (%100)	10/12 (%83.3)	8/9 (%88.8)	1/1 (%100)	5/5 (%100)	7/7 (%100)

CCHD, Critical congenital heart diseases; TOF, Tetralogy of fallot; PA, Pulmonary atresia; AS, Aortic stenosis; TA, Tricuspid atresia; HLHS, hypoplastic left heart syndrome; IAA, interrupted aortic arch; TGA, Transposition of the great arteries; ECHO, Echocardiography; PE, Physical examination

12 Evaluation of Critical Congenital Heart Disease Screening Results with Pulse Oximetry

Kara N, Arman D, Gül A, Şimşek T, Ceylan Ö, Cömert S. *İstanbul Med J*. 2022; 23(2): 102-6.

Introduction

The early diagnosis and treatment of critical congenital heart diseases (CCHD), which require surgery or intervention during the 1st year of life, is an important issue. Screening of CCHD with pulse oximetry increases early diagnosis rates. Therefore, our [investigators'] study aimed to evaluate the results of CCHD screening with pulse oximetry among babies born in our [investigators'] hospital.

Methods

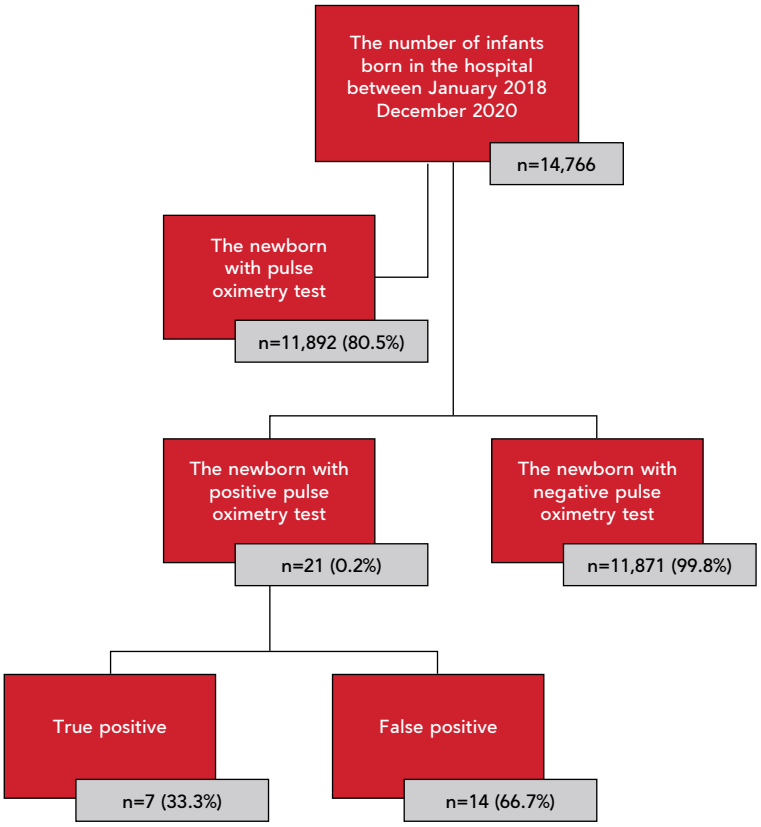
The results of the CCHD screening with pulse oximetry of the babies with a gestational age of ≥34 weeks that were born in our [investigators'] hospital between January 1, 2018, and December 31, 2020, were retrospectively evaluated.

Results

Among the 14,766 babies born during the study period, the screening results of 11,892 babies were evaluated; 5,826 of whom were female (48.9%), and 6,066 (51.1%) were male. The number of babies who passed the screening test was 11,871 (99.8%), whereas 21 (0.2%) failed. Among 21 babies who failed the screening test and were evaluated by echocardiography, 7 (33.3%) babies were found to have CCHD. Preductal and postductal saturation values were found to be significantly lower in patients with the positive screening test and in whom CCHD was detected, compared with those without CCHD.

Conclusion

Early diagnosis of CCHD before discharge is possible with pulse oximetry screening. Better prognosis and lower mortality rates are targeted with early diagnosis in these babies. Therefore, arrangements should be made for the screening of all newborn babies with pulse oximetry.



Screening test results of newborns screened with pulse oximetry

13 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.

14 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 $>\pm 3\%$ 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 [Investigators'] 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.

15 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 (SpO_2) and performed machine-generated (MG) and volunteer-generated (VG) hand movements with the test hand, keeping the control hand stationary. **Measurements:** SpO_2 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 SpO_2, 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 SpO_2 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 SpO_2 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 SpO_2 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 SpO_2 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 SpO_2 sensitivity and specificity than the Nellcor N-600 and Datex-Ohmeda TruSat during conditions of motion and induced low perfusion in this volunteer study.

16 "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 [study investigators] 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

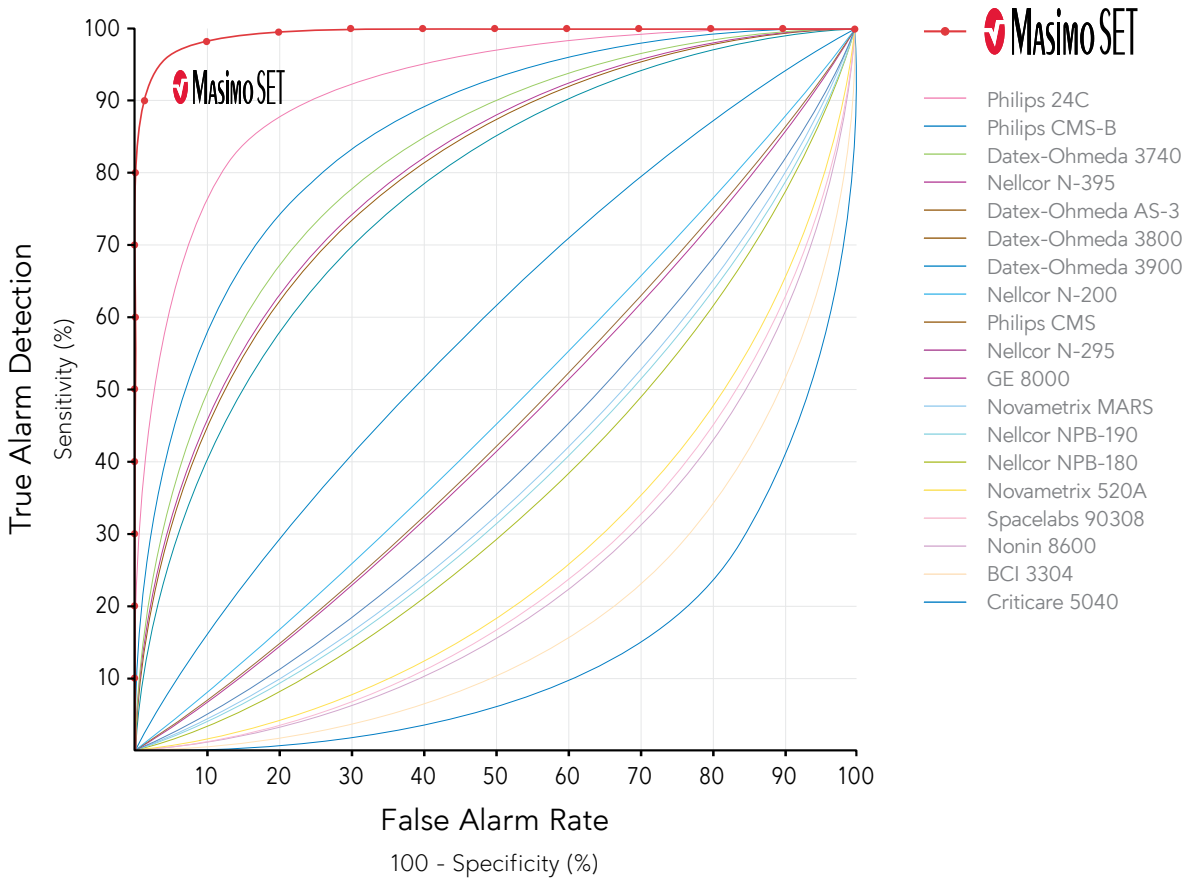
The Masimo SET pulse oximeter exhibited the best overall performance, with a performance index (percentage of time in which the SpO_2 reading is within 7% of control value) of 94%. The Philips Viridia 24C was next, with an 84% index, followed by the Philips CMS (80%), the Datex-Ohmeda 3740 (80%), and 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"

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.

Results



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.

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.

17 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

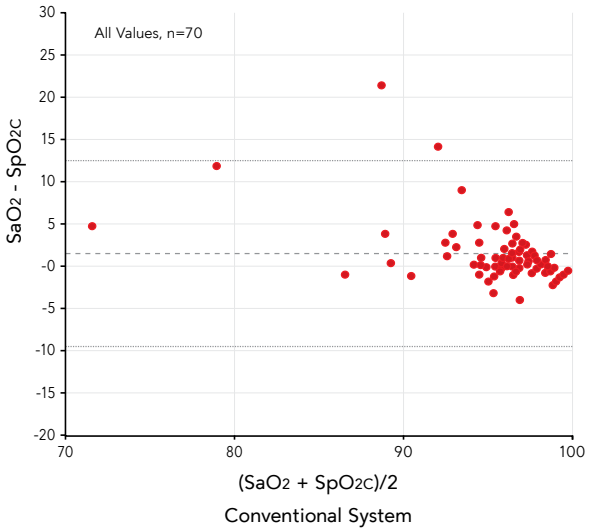
Pulse oximeters are routinely used in severely ill patients to detect hypoxemia early. In various clinical situations, however, conventional devices may be unable to display valid values or any value whatsoever. The usefulness of the Signal Extraction Technology (SET) in these situations has not yet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

Methods

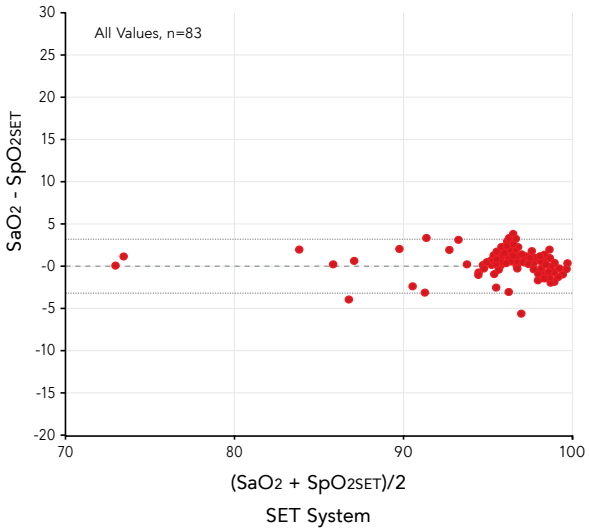
Twenty-five adult patients requiring norepinephrine, regardless of the reason or dosage, or having a defective signal with a conventional oximeter were equipped with both their conventional saturation sensor (Oxymax Nellcor) and a SET saturation sensor (Masimo) connected to its monitor. Saturation values 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 $\pm$ 2 SD of 0.0% $\pm$ 3.1% vs 2.1% $\pm$ 11.0%, respectively), even when only valid values (values accompanied by a satisfactory quality index) were considered (0.0% $\pm$ 2.7% vs 1.2% $\pm$ 7.0%).



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



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.

18 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.

19 Reliability of Conventional and New Pulse Oximetry in Neonatal Patients

M

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 [study investigators] 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 [investigators] 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 [study investigators] 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 [study investigators] 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.

20 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 [study investigators] 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 $\pm$ 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.

21 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

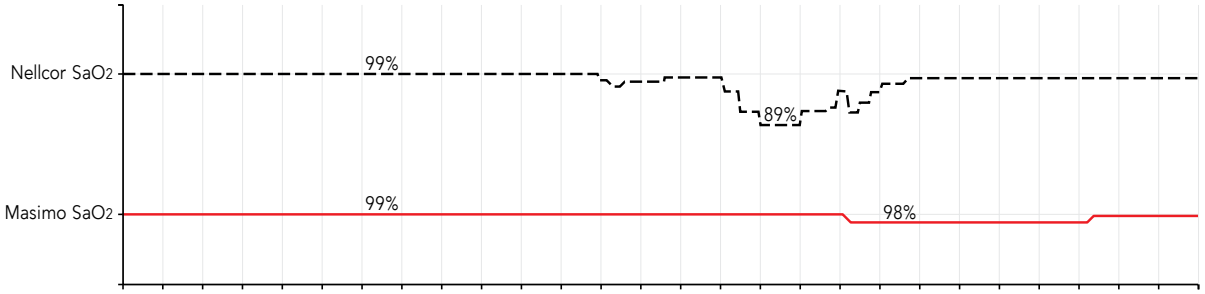
Newer pulse oximeters have been developed to be motion resistant and thus have few false alarms. However, they have not yet been evaluated in a pediatric sleep laboratory setting. While evaluating new oximeters for use in our [investigators'] laboratory, we [study investigators] obtained simultaneous 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 $\pm$ 2.4% vs 5.5 $\pm$ 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.

22 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.

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

Method	All SaO_2 Values	SaO_2 ≤ 75%	75% < SaO_2 ≤ 85%	SaO_2 ≥ 85%
	% (*n*)	% (*n*)	% (*n*)	% (*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.

23 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 [study investigators] 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 ± 4.4 vs. 3.9 ± 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 ± 2.2	0.6; 7.2	8.2 ± 3.62	3.4; 20.4
Magdeburg	4.9 ± 2.3	1.8; 8.2	11.5 ± 4.5	4.6; 17.8
All	**3.9** ± 2.3	2.5; 5.8	**9.05** ± 4.4	7.2; 11.8

Bold implies $p<0.05$ is significant.

Conclusion

We [study investigators] 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.

24 Experiences from an Implementation Model of ARI Diagnostic Device in Pneumonia Case Management Among Under-5 Children in Peripheral Healthcare Centers in India

Kumar H, Sarin E, Saboth P, Jaiswal A, Chaudhary N, Mohanty JS, Bisht N, Tomar SS, Gupta A, Panda R, Patel R, Kumar A, Gupta S, Alwadhi V. *Clin Med Insights Pediatr*. 2021 Nov 15;15:11795565211056649.

Objectives

To address pneumonia, a major killer of under-5 children in India, a multimodal pulse oximeter was implemented in Health and Wellness Centers. Given the evidence of pulse oximetry in effective pneumonia management and taking into account the inadequate skills of front-line healthcare workers in case management, the device was introduced to help them readily diagnose and treat a child and to examine usability of the device.

Design

The implementation was integrated with the routine OPD of primary health centers for 15 months after healthcare workers were provided with an abridged IMNCI training. Monthly facility data was collected to examine case management with the diagnostic device. Feedback on usefulness of the device was obtained.

Setting

Health and Wellness Centers (19) of 7 states were selected in consultation with state National Health Mission based on patient footfall.

Participants

Under-5 children presenting with ARI symptoms at the OPD.

Results

Of 4846 children, 0.1% were diagnosed with severe pneumonia and 23% were diagnosed with pneumonia. As per device readings, correct referrals were made of 77.6% of cases of severe pneumonia, and 81% of pneumonia cases were correctly given antibiotics. The Pulse oximeter was highly acceptable among health workers as it helped in timely classification and treatment of pneumonia. It had no maintenance issue and battery was long-lasting.

Conclusion

Pulse oximeter implementation was doable and acceptable among health workers. Together with IMNCI training, PO in primary care settings is a feasible approach to provide equitable care to under-5 children.

Correct case management of children with severe pneumonia (general danger signs or hypoxia (SpO2<90).

Age Group	Total Referral	Total Cases with SpO2<90	Cases with SpO2<90 and Referred	Total Cases with General Danger Sign	Cases with General Danger Sign and Referred	Cases with SpO2<90 or Danger Sign and Referred	Valid Cases Referred	Total Correctly Referred N (%)	Referral Compliance (%)
2 months to 1 year	21	16	12	10	8	17	2	19 (90.5)	14 (82.4)
1-5 years	28	13	8	28	13	16	3	19 (67.9)	11 (68.8)
Total	49	29	20	38	21	33	5	38 (77.6)	25 (75.8)

Correct case management of children with pneumonia (fast breathing or chest indrawing symptoms).

Age Group	Total Antimircobials Given	Total Cases with Fast Breathing	Cases of Fast Breathing Given Antibiotics	Total Cases with Chest Indrawing	Cases with Chest Indrawing Given Antibiotics	Cases with Fast Breathing or Chest Indrawing Given Antibiotics	Other Valid Reasons for Antibiotics	Total Correctly Given Antibiotics N (%)
<2 months	13	9	7	0	0	7	0	7 (53.8)
2 months to 1 year	380	372	299	55	44	299	4	303 (78.7)
1-5 years	927	902	780	86	73	763	0	763 (82.3)
Total	1320	1283	1086	141	117	1069	4	1073 (81.0)

25 Evaluation of Perfusion Index as a Screening Tool for Developing Critical Limb Ischemia

Yamamoto N, Sakashita H, Miyama N, Takai K, Komai H. *Ann Vasc Dis*. 2021 Dec 25;14(4):328-333.

Objective

The perfusion index (PI) is a physiological marker for evaluating the peripheral circulation. We [study investigators] explored the possibility of using PI as a screening tool for development of critical limb ischemia in peripheral artery disease (PAD).

Methods

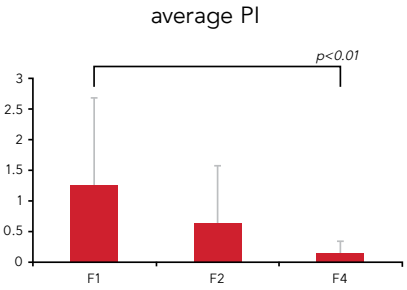
We [study investigators] measured the PI in 79 limbs of 70 PAD patients. Data were analyzed to find a correlation between the PI and PAD severity.

Results

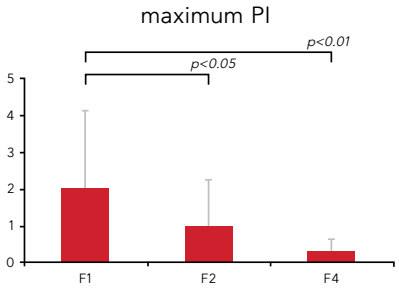
The PI tended to be lower as PAD became severer. Especially, there were significant differences between the Fontaine 1 and Fontaine 4 groups in average PI and minimum PI, and between Fontaine 1 and two other groups (Fontaine 2 and Fontaine 4 groups) in maximum PI. A mild correlation was found between PI and the ankle brachial index. These data were used to calculate an average PI of 0.27 as a cut-off value for critical limb ischemia (CLI). In 65 asymptomatic PAD patients and claudication, significantly more patients with a PI value greater than the cut-off value developed CLI than those with a PI lower than the cut-off.

Conclusion

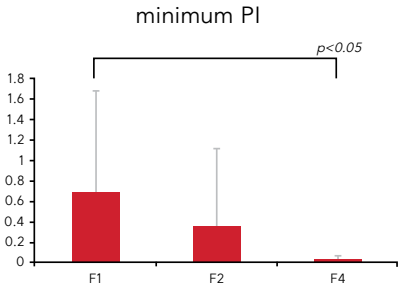
The PI can be a useful tool for evaluating the development of CLI in mild PAD patients, and patients tended not to progress to CLI when their average PI was higher than 0.27.



Univariate correlation of PI average value. PI average value in F1 group is significantly higher than that in F4 group.



Univariate correlation of PI maximum value. PI maximum value in F1 group is significantly higher than those in other two groups, but there is no significant difference between F2 and F4 group.



Univariate correlation of PI minimum value. PI minimum value in F1 group is significantly higher than that in F4 group.

26 Perfusion Index Measurement in Predicting Hypovolemic Shock in Trauma Patients

Ozakin E, Yazlamaz NO, Kaya FB, Karakilic EM, Bilgin M. *J Emerg Med*. 2020 Aug;59(2):238-245.

Background

Perfusion index (PI) derived from pulse oximeter shows the ratio of the pulsatile blood flow to the nonpulsatile blood flow or static blood in peripheral tissue.

Objectives

The aim of this study was to investigate the relationship between PI and blood transfusion necessity in 24 h and stage of hemorrhagic shock, as well as the utility of PI according to laboratory and clinical parameters, and determining the major risk of hemorrhage.

Methods

PI was measured with a pulse oximeter in 338 patients (235 males, average age 41.8 ± 17.94 years). Laboratory parameters (hemoglobin, hematocrit, lactate, base deficits, pH) and clinical parameters (pulse rate, respiratory rate, SpO_2, systolic blood pressure [SBP] and diastolic blood pressure [DBP]), shock index (SI) and revised trauma score (RTS) were recorded. Univariate analysis was used to determine major risk for bleeding, and the receiver operating characteristic curves were performed to compare parameters.

Results

PI was < 1 in 39 (11.5%) patients. Positive correlation between PI and hemoglobin ($p < 0.001$; r: 0.320), hematocrit ($p < 0.001$; r: 0.294), base deficit ($p < 0.001$; r: 0.315), pH ($p < 0.05$; r: 0.235), SBP ($p < 0.001$; r: 0.146), DBP ($p < 0.001$; r: 0.259), SpO_2 ($p < 0.001$; r: 0.197), RTS ($p < 0.001$; r: 0.344), and negative correlation with lactate ($p < 0.05$; r: -0.117), pulse ($p < 0.001$; r: -0.326), respiratory rate ($p < 0.001$; r: -0.231), and SI ($p < 0.001$; r: -0.257) were detected. A difference was detected between class 1 and 2, and class 1 and 3 (both $p < 0.05$) in hemorrhagic shock. Thirty-one with PI < 1 had blood transfusion within 24 h ($p < 0.001$; odds ratio 111.98, sensitivity 75.6%, specificity 97.3, positive predictive value 79.5%, negative predictive value 96.7%). The main risk factors of the need for blood transfusions were PI, pulse rate, and SpO_2. PI was more significant than lactate, base deficit, RTS, and SI measurements.

Conclusion

PI might be beneficial in the detection and exclusion of critical patients and blood transfusion needs in the emergency department. PI can be used with vital signs and shock parameters in the early diagnosis of hemorrhage.

Perfusion Index and Blood Transfusion in 24 Hours Comparison

	PI < 1 n = 39 (%)	PI > 1 n = 299 (%)	*p* Value	OR (95% CI)	Sensitivity (%)	Specificity (%)	PPV (%)	LR+	NPV (%)	LR−
Blood transfusion in 24 h (n = 41)	32 (82.1)	9 (3)	< 0.001	147.3(51.3–422.2)	78	97.6	82.1	33	97	0.22

PI = perfusion index; OR = odds ratio; CI = confidence interval; PPV = positive predictive value; LR = likelihood ratio; NPV = negative predictive value.

27 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 [study investigators] 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 [study investigators] conducted a case-control study. **Setting:** Our [investigators'] 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 [study investigators] 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	0.65	2.15
Hypoplastic Left Heart Syndrome	0.82	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.

28 Oxygen Saturation and Perfusion Index-Based Enhanced Critical Congenital Heart Disease Screening

Siefkes H, Kair L, Tancredi DJ, Vasquez B, Garcia L, Bedford-Mu C, Lakshminrusimha S. *Am J Perinatol*. 2020 Jan;37(2):158-165.

Objective

To determine if addition of perfusion index (PIx) to oxygen saturation (SpO_2) screening improves detection of critical congenital heart disease (CCHD) with systemic outflow obstruction.

Study Design

We [study investigators] determined screening thresholds for PIx and applied these to a cohort of newborns with and without congenital heart disease (CHD).

Results

A total of 123 normal and 21 CHD newborns (including five with critical systemic outflow obstruction) were enrolled. Four of these five critical systemic obstruction subjects passed SpO_2-based screen. Four out of these five subjects failed PIx-based screen. The sensitivity for detection of systemic obstruction CCHD when compared with healthy infants increased from 20% (95% confidence interval [CI]: 1-72%) with SpO_2 screening alone to 80% (95% CI: 28-100%) with combined SpO_2-PIx screen. However, 2.44% of normal infants failed PIx screen.

Conclusion

Addition of PIx to SpO_2 screening may detect additional cases of CCHD and further research is necessary to come up with optimal screening thresholds.

Sensitivity and specificity of oxygen saturation and perfusion index screening for congenital heart defects

	Oxygen saturation alone	Oxygen saturation + perfusion index[a]	*p*-Value
Critical congenital heart defects[b] (*N* = 13)			
Sensitivity, % (95% CI)	62 (32-86)	85 (55-98)	0.08
Sensitivity difference, % (95% CI)	Reference	23 (−8 to +54)	NA
Critical congenital heart defects with systemic obstruction[b] (*N* = 5)			
Sensitivity, % (95% CI)	20 (1-72)	80 (28-100)	0.08
Sensitivity difference, % (95% CI)	Reference	+60 (−3 to 100)	NA
All congenital heart defects[b] (*N* = 21)			
Sensitivity, % (95% CI)	38 (18-62)	71 (48-89)	**0.008**
Sensitivity difference, % (95% CI)	Reference	+33 (+8 to 58)	NA
No-CHD (*N* = 123)			
Sensitivity, % (95% CI)	100 (97-100)	98 (93-100)	0.08
Sensitivity difference, % (95% CI)	Reference	−2 (−6 to +1)	NA

Abbreviations: CI, confidence interval; CHD, congenital heart disease.
[a]Perfusion index result = fail if postductal perfusion index < 0.5.
[b]For all comparison, McNemar's test was used to produce *p*-value and effect size and 95% CI were estimated using methods for paired binary data.

29 The Value of Peripheral Perfusion Index Measurements for Early Detection of Critical Cardiac Defects

Uygur O, Koroglu OA, Levent E, Tosyali M, Akisu M, Yalaz M, Kultursay N. *Pediatr Neonatol*. 2019 Feb;60(1):68-73.

Background

Approximately 25% of congenital heart diseases (CHD) are estimated to be critical and require an intervention. In this study, we [study investigators] aimed to investigate the additional value of peripheral perfusion index (PPI) measurements to pulse oximetry screening for critical CHD (CCHD).

Methods

Infants born at Ege University Hospital between May 2013 and September 2015 were prospectively included in the study. In addition to physical examination, pre- and postductal oxygen saturations and PPI values were measured with a new generation pulse oximeter before discharge from the hospital.

Results

A total of 3175 newborns (33 with an antenatal diagnosis of CCHD) were included in the study. With the combination of physical examination, pulse oximetry screening and peripheral perfusion index (PPI) measurements, all newborns with CCHD were detected in our [investigators'] study including three infants without an antenatal diagnosis in whom pulse oximetry screening was negative.

Conclusion

PPI measurements may be valuable for early detection of obstructive left heart lesions where pulse oximetry screening has limitations in diagnosis.

Analysis of cut-off values for pre- and post-ductal measurements.

	Sensitivty (%)	Specificity (%)	PPV (%)	NPV (%)	Number of missed patients in primary targets of CCHD	Number of missed patients in secondary targets of CCHD
Cut-off values for pre-ductal measurements						
5 p (1.2)	63.6	97.2	19.4	99.6	8	4
0.7	33.3	99.2	30.6	99.3	15	7
1	57.5	98.5	22.8	99.5	7	7
Cut-off values for post-ductal measurements						
5 p (1.1)	60.6	96.3	14.8	99.5	8	5
0.7	36.4	98.4	19.4	99.3	13	8
1	57.5	96.3	14.3	99.5	9	5

30 Comparison of Perfusion Index and Echocardiographic Parameters in Preterm Infants with Hemodynamically Significant Patent Ductus Arteriosus

Buyukeren Melek, Şule Yiğit, Hayrettin Hakan Aykan, Tevfik Karagöz, Hasan Tolga Çelik, Murat Yurdakök. *J Clin Neonatology*. 2021;10(1):11-18.

Background/Aim

The aim of the study was to compare echocardiographic parameters and the perfusion index (PI) and plethysmographic variability index (PVI) values obtained by routine pulse oximetry in the diagnosis of hemodynamically significant patent ductus arteriosus (hsPDA).

Materials and Methods

This prospective study was conducted between 2016 and 2017 at the HacettepeUniversity Neonatal Intensive Care Unit. The study included premature neonates who had a birth weight below 1500 g. Patients were routinely monitored from the right wrist and right foot using a pulse oximeter (Masimo Radical-7® Pulse CO-Oximetry), and PI and PVI values were recorded. The difference between right-hand and right-leg PI values was calculated as the delta PI (ΔPI). A cardiologist blinded to the results evaluated the presence of patent ductus arteriosus (PDA) with echocardiography on postnatal days 1th, 3rd, and 7th.

Results

Of the 66 preterm neonates included in the study, 23 had hsPDA. On postnatal day 1, the hsPDA group had a significantly greater ductal diameter, PDA/left pulmonary artery (LPA) ratio, and left ventricle (LA)/aortic (Ao) ratio ($P < 0.05$). On day 7, the hsPDA group had a significantly higher ductal velocity, PDA/LPA ratio, LA/Ao ratio, antegrade PA and LPA diastolic flow, and LV/Ao ratio ($P < 0.05$). In hsPDA group, the median ΔPI values were 0.85 (25–75 interquartile range [IQR]; 0.62–1.15) on day 1; 1.03 (25–75 IQR; 0.85–1.26) on day 3; and 0.89 (25–75 IQR; 0.64–1.22) on day 7. The median (25–75 IQR) ΔPI values were higher in the hsPDA group than in the non-hsPDA group on postnatal days 1, 3, and 7 ($P < 0.001$, $P < 0.001$, and $P < 0.001$, respectively). The ΔPI cutoff values for the diagnosis of hsPDA were 0.47 on day 1 (91.3% specificity; 90.5% sensitivity), 0.41 on day 3 (100% specificity; 97.3% sensitivity), and 0.47 on day 7 (90% specificity; 100% sensitivity).

Conclusion

Our [investigators'] study shows that the difference between PI values (ΔPI) in the right hand and right leg obtained by pulse oximetry has diagnostic value in hsPDA and can assist diagnosis when echocardiography is not available.

Correlation analysis of pulse oximetry and echocardiography data in the hemodynamically significant patent ductus arterosus (+) group

Pulse oximetry measurements	Echocardiography measurements (*r*, *P*)			
	Transductal diameter	PDA/LPA diameter	Left atrial: Aortic ratio	Antegrade LPA diastolic flow
Day 1				
ΔPI	0.261, 0.037	0.159, 0.210	0.246, 0.05	0.316, 0.011
PVI (right hand)	−0.047, 0.708	0.013, 0.92	0.046, 0.715	0.165, 0.188
PVI (right leg)	−0.017, 0.892	0.056, 0.656	0.216, 0.084	0.139, 0.269
Day 3				
ΔPI	0.629, 0.000	0.278, 0.036	0.430, 0.002	0.561, 0.000
PVI (right hand)	0.224, 0.088	0.161, 0.224	0.241, 0.095	−0.039, 0.790
PVI (right leg)	0.220, 0.095	0.131, 0.323	0.267, 0.063	0.069, 0.636
Day 7				
ΔPI	0.801, 0.000	0.712, 0.000	0.489, 0.002	0.534, 0.000
PVI (right hand)	0.518, 0.000	0.526, 0.000	0.297, 0.067	0.100, 0.544
PVI (right leg)	0.281, 0.038	0.273, 0.044	0.157, 0.340	0.165, 0.316

LPA - Left pulmonary artery; PI - Perfusion index; PVI - Plethysmographic variability index; PDA - Patent ductus arteriosus; ΔPI - Delta perfusion index

31 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

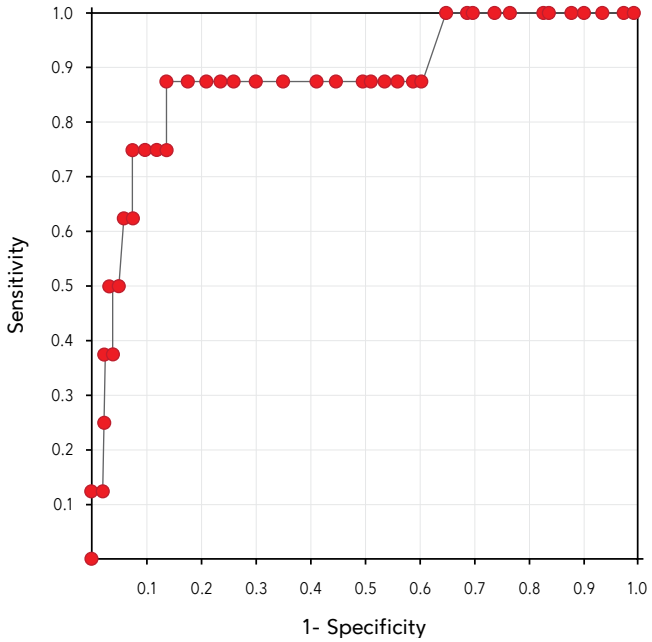
Superior vena cava (SVC) flow is used as an index for evaluating systemic blood flow in neonates. Thus far, several reports have shown that low SVC flow is a risk factor for intraventricular hemorrhage (IVH) in the preterm infant. Therefore, it is likely to be a useful index in the management of the 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 [investigators] 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%).



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.

32 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

33 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 [study investigators] 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

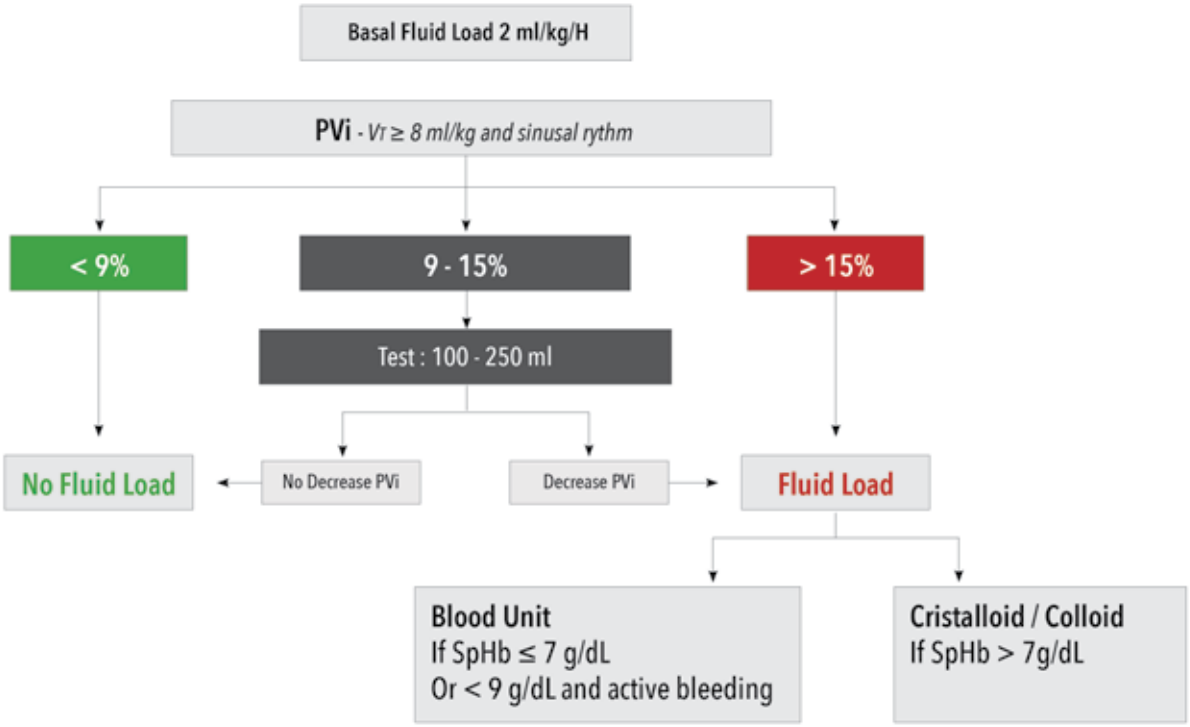
A decreased perfusion index value in the pre-anesthesia phase of elective cesarean section is a maternal predictor of increased neonatal morbidity and is significantly related to subclinical placental inflammatory disease. These observations suggest the feasibility of a noninvasive pulse oximeter prenatal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

34 Continuous Hemoglobin and Plethysmography Variability Index Monitoring Can Modify Blood Transfusion Practice and is Associated With Lower Mortality

Cros, J., Dalmay, F., Yonnet, S. et al. *J Clin Monit Comput* 2019.

Abstract

To determine the effect of implementing an algorithm of fluid and blood administration based on continuous monitoring of hemoglobin (SpHb) and PVI (plethysmography variability index) on mortality and transfusion on a whole hospital scale. This single-center quality program compared transfusion at 48 h and mortality at 30 days and 90 days after surgery between two 11-month periods in 2013 and 2014 during which all the operating and recovery rooms and intensive care units were equipped with SpHb/PVI monitors. The entire team was trained to use monitors and the algorithm. Team members were free to decide whether or not to use devices. Each device was connected to an electronic wireless acquired database to anonymously acquire parameters on-line and identify patients who received the monitoring. All data were available from electronic files. Patients were divided in three groups; 2013 (G1, n = 9285), 2014 without (G2, n = 5856) and with (G3, n = 3575) goal-directed therapy. The influence of age, ASA class, severity and urgency of surgery and use of algorithm on mortality and blood use were analyzed with cox-proportional hazard models. Because in 2015, SpHb/PVI monitors were no longer available, we [study investigators] assessed post-study mortality observed in 2015 to measure the impact of team training to adjust vascular filling on a patient to patient basis. During non-cardiac surgery, blood was more often transfused during surgery in G3 patients as compared to G2 (66.6% vs. 50.7%, p < 0.001) but with fewer blood units per patient. After adjustment, survival analysis showed a lower risk of transfusion at 48 h in G3 [OR 0.79 (0.68–0.93), p = 0.004] but not in G2 [OR 0.90 (0.78–1.04) p = 0.17] as compared to G1. When adjusting to the severity of surgery as covariable, there was 0.5 and 0.7% differences of mortality at day 30 and 90 whether patients had goal directed therapy (GDT). After high risk surgery, the mortality at day 30 is reduced by 4% when using GDT, and 1% after intermediate risk surgery. There was no difference for low risk surgery. G3 Patients had a lower risk of death at 30 days post-surgery [OR 0.67 (0.49–0.92) p = 0.01] but not G2 patients [OR 1.01, (0.78–1.29), p = 0.96]. In 2015, mortality at 30 days and 90 days increased again to similar levels as those of 2013, respectively 2.18 and 3.09%. Monitoring SpHb and PVI integrated in a vascular filling algorithm is associated with earlier transfusion and reduced 30 and 90-day mortality on a whole hospital scale.



Algorithm of blood transfusion and fluid management according to results of SpHb and pulse pressure variation.

35 Monitoring of Plethysmography Variability Index and Total Hemoglobin Levels During Cesarean Sections with Antepartum Hemorrhage For Early Detection of Bleeding

Ahmed Elsakka, Wael Hossam, Gehan Helmy, Nadia Helmy. *Egyptian J Anaesthes*. 2017;33(1): 5-8

Background

Cesarean sections for parturients with antepartum hemorrhage have the potential risk of massive blood loss. In the current study we [study investigators] investigated the use of Plethysmography variability index (PVI) and non invasive hemoglobin (SPHB) monitoring as well for intraoperative detection of blood loss and intravascular volume status.

Methods

One hundred and twenty four full term parturients scheduled for elective CS were included in the study. All patients received general anesthesia after preoxygenation for 5 min, rapid-sequence induction performed with thiopental 3–5 mg/kg and suxamethonium 1.5 mg/kg; Anesthesia was maintained with a 100% of oxygen with 0.5–1 MAC of isoflurane and atracurium 0.5 mg/kg. Standard monitors (pulse oximetry, non-invasive blood pressure, and ECG) were applied. Masimo sensor was applied following best practice guidelines, and automated data collection (ADC) was done. Our [investigators'] primary outcome was to compare PVI values before versus after administration of fluids and blood that was given based on clinical data. Our [investigators'] secondary outcome was to review of SPHb traces plots to determine if and when SpHb may have detected presence of anemic state or critical drop in hemoglobin level when compared to time of clinical awareness of bleeding and confirmation by lab Hb sample measurement.

Results

PVI showed a significant negative correlation with CVP ($p = 0.037$) and a significant negative correlation with MAP ($p = 0.01$). Also, it showed significant positive correlation with HR ($p < 0.001$). A highly significant Correlation was found between pre transfusion lab Hb and pre transfusion SpHb ($p < 0.001$). Also post transfusion values showed a highly significant correlation as well ($p < 0.001$). A total of 87 transfusions (91.58%) were found unnecessary when using SpHb as the reference, compared to 58 (61.05%) when using the invasive laboratory measurement.

Conclusion

Plethysmography variability index and non invasive hemoglobin monitoring as well can be used for optimization of intravascular volume status during cesarean sections in parturients with antepartum hemorrhage.

Fig. 1

Fig. 2

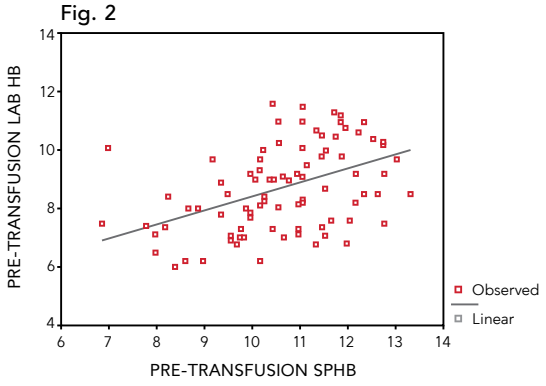


Fig. 3

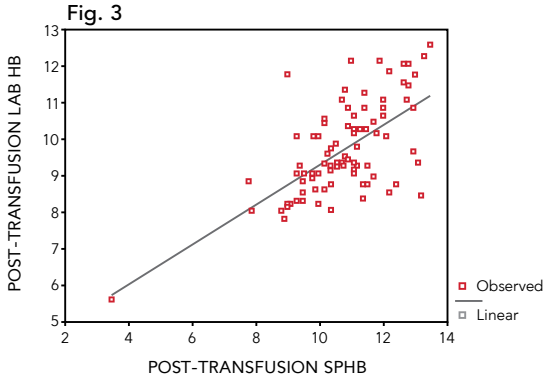


Figure 1. Linear regression curve showing significant positive correlation between PVI & HR (heart rate).

Figure 2. Linear regression curve showing significant positive correlation between pre transfusion lab HB and pre transfusion SpHB.

Figure 3. Linear regression curve showing significant positive correlation between post transfusion lab HB and post transfusion SpHB.

36 Standardization of Care: Impact of an Enhanced Recovery Protocol on Length of Stay, Complications, and Direct Costs After Colorectal Surgery

Thiele RH, Rea KM, Turrentine FE, Friel CM, Hassinger TE, McMurry TL, Goudreau BJ, Umapathi BA, Kron IL, Sawyer RG, Hedrick TL. *J Am Coll Surg*. 2015 Apr;220(4):430-43.

Background

Colorectal surgery is associated with considerable morbidity and prolonged length of stay (LOS). Recognizing the need for improvement, we [study investigators] implemented an enhanced recovery (ER) protocol for all patients undergoing elective colorectal surgery at an academic institution.

Study Design

A multidisciplinary team implemented an ER protocol based on: preoperative counseling with active patient participation, carbohydrate loading, multimodal analgesia with avoidance of intravenous opioids, intraoperative goal-directed fluid resuscitation, immediate postoperative feeding, and ambulation. Discharge requirements remained identical throughout. A before and after study design was undertaken comparing patients before (August 2012 to February 2013) and after implementation of an ER protocol (August 2013 to February 2014). Risk stratification was performed using the NSQIP risk calculator to calculate the predicted LOS for each patient based on 23 variables.

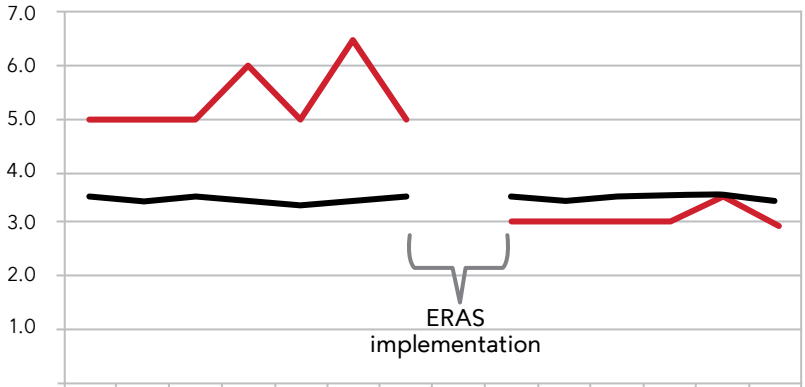
Results

One hundred and nine consecutive patients underwent surgery within the ER protocol compared with 98 consecutive historical controls (conventional). The risk-adjusted predicted LOS was similar for each group at 5.1 and 5.2 days. Substantial reductions were seen in LOS, morphine equivalents, intravenous fluids, return of bowel function, and overall complications with the ER group. There was a $7,129/patient reduction in direct cost, corresponding to a cost savings of $777,061 in the ER group. Patient satisfaction as measured by Press Ganey improved considerably during the study period.

Conclusions

Implementation of an ER protocol led to improved patient satisfaction and substantial reduction in LOS, complication rates, and costs for patients undergoing both open and laparoscopic colorectal surgery. These data demonstrate that small investments in the perioperative environment can lead to large returns.

Length of stay (LOS) for colorectal surgery patients relative to the medical center as a whole.



	Aug. 2012	Sept. 2012	Oct. 2012	Nov. 2012	Dec. 2012	Jan. 2013	Feb. 2013		Aug. 2013	Sept. 2013	Oct. 2013	Nov. 2013	Dec. 2013	Jan. 2014
Median Length of Stay Colorectal Surgery Patients	5.0	5.0	5.0	6.0	5.0	6.5	5.0		3.0	3.0	3.0	3.0	3.5	3.0
Median Length of Stay Entire Hospital	3.5	3.4	3.5	3.4	3.4	3.4	3.5		3.5	3.4	3.5	3.5	3.6	3.4

EERAS, enhanced recovery after surgery.

37 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 [study researchers] 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.

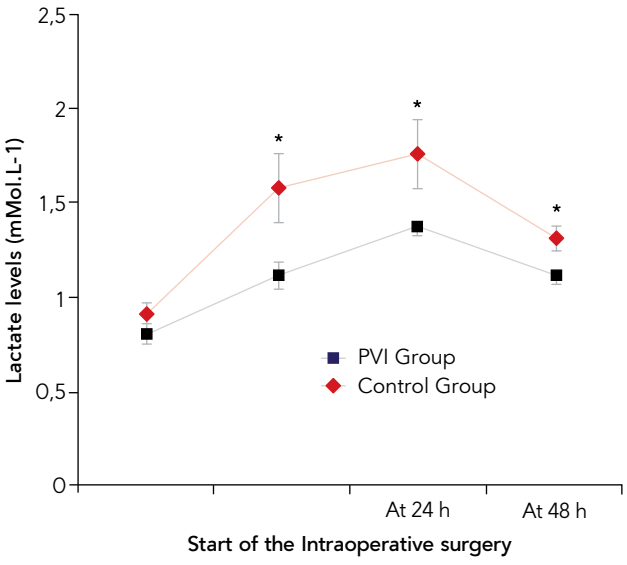
Methods

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



Intraoperative: maximum intraoperative value.

Data are presented as mean +/- SEM. *P < 0.05.

Conclusion

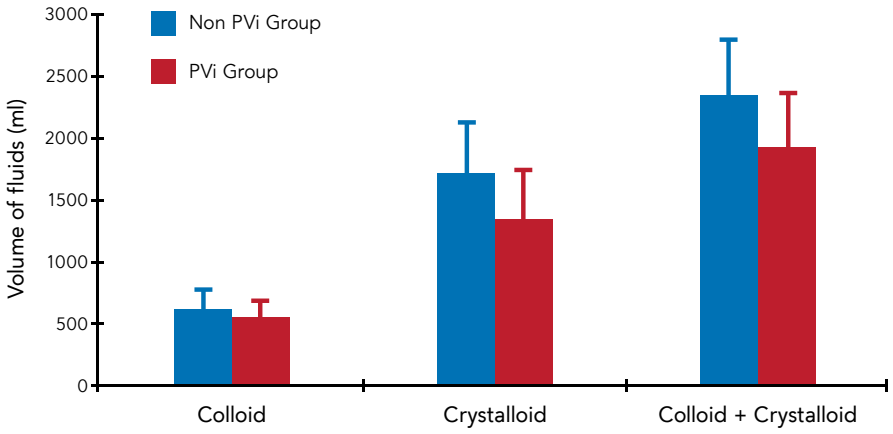
PVi-based, goal-directed fluid management reduced the volume of intraoperative fluid infused and reduced intraoperative and postoperative lactate levels.

Masimo-supported Study

38 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 [investigators'] 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.



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

39 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 [study investigators] hypothesized that PVi can predict fluid responsiveness in mechanically ventilated patients under general anaesthesia.

Methods

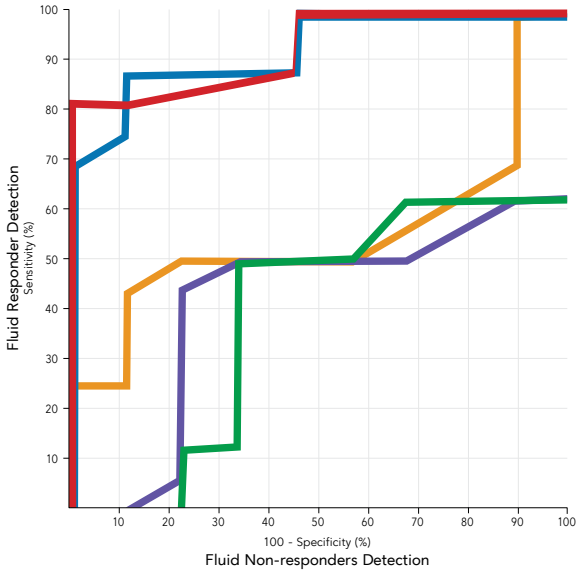
Twenty-five patients were studied after induction of general anaesthesia. Haemodynamic data {cardiac index [CI], respiratory variations in arterial pulse pressure [ΔPP], ΔPOP, and PVi} were recorded before and after volume expansion (500 mL of hetastarch 6%). Fluid responsiveness was defined as an increase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



Pleth Variability Index (PVI)

Arterial Pulse Pressure Variation (PVV)

Cardiac Index (CI)

Pulmonary Capillary Wedge Pressure (PCWP)

Central Venous Pressure (CVP)

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.

Masimo-supported Study

40 Prediction of Fluid Responsiveness in Mechanically Ventilated Patients in Surgical Intensive Care Unit by Pleth Variability Index and Inferior Vena Cava Diameter

Aboelnile DBMK, Elseidy MIA, Kenawey YAEM, Elsherif IMAA. *Ain-Shams J Anesthesiol*. 2020;12(1):48.

Background

Patients may have signs of hypovolemia, but fluid administration is not always beneficial. We [clinicians] are in need of bedside devices and techniques, which can predict fluid responsiveness effectively and safely. This study is aiming to compare the effectiveness and reliability of the pleth variability index (PVI) and IVC distensibility index (dIVC) as predictors of fluid responsiveness by simultaneous recordings in all sedated mechanically ventilated patients in the surgical intensive care unit (ICU). We [study investigators] used the passive leg raising test (PLR) as a harmless reversible technique for fluid challenge, and patients were considered responders if the cardiac index (CI) measured by transthoracic echocardiography (TTE) increased ≥ 15% after passive leg raising test (PLR).

Results

This observational cross-sectional study was performed randomly on 88 intubated ventilated sedated patients. Compared with CI measured by transthoracic echocardiography, the dIVC provided 79.17% sensitivity and 80% specificity at a threshold value of > 19.42% for fluid responsiveness prediction and was statistically significant (P < .0001), with an area under the curve (AUC) of 0.886 (0.801–0.944), while PVI at a threshold value of > 14% provided 93.75% sensitivity and 87.5% specificity and was statistically significant (P < .0001), with an AUC of 0.969 (0.889–0.988).

Conclusion

PVI and dIVC are effective non-invasive bedside methods for the assessment of fluid responsiveness in ICU for intubated ventilated sedated patients with sinus rhythm, but PVI has the advantage of being continuous, operator-independent, and more reliable than dIVC.

The comparison of performances between parameters

Parameters	CVP	PVI	dIVC
Threshold values	≥ 5 mmHg	> 14%	> 19.42%
Sensitivity (%)	70.83	93.75	79.17
Specificity (%)	47.50	87.50	80
AUC (95% CI)	0.612 (0.502–0.714)	0.955 (0.889–0.988)	0.886 (0.801–0.944)
LR+	1.35	7.50	3.96
LR–	0.61	0.071	0.26
PPV	61.82	90	82.61
NPV	57.58	92.12	76.19
P	0.0648	< 0.0001	< 0.0001

AUC (95% CI) area under ROC curve (95% CI), *CVP* central venous pressure, *dIVC* caval index, *LR* likelihood ratio, *NPV* negative predictive value, *PPV* positive predictive value, *PVI* pleth variability index

41 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 [study investigators] 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.

42 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

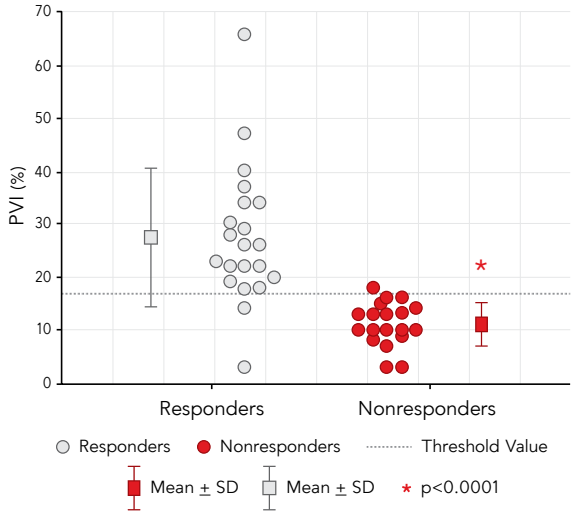
To investigate whether the pleth variability index, a noninvasive and continuous tool, can predict fluid responsiveness in mechanically ventilated patients with circulatory insufficiency.

Methods

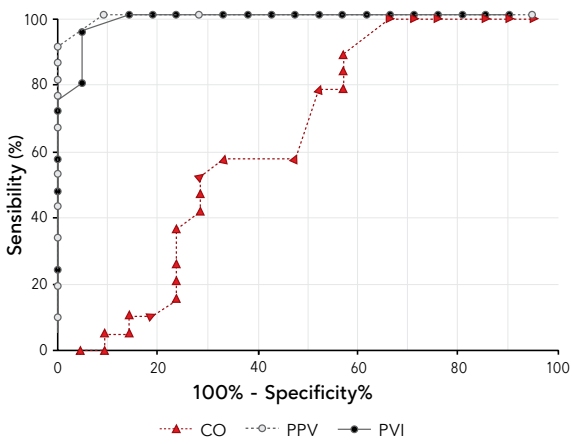
Design: Prospective study. **Setting:** Surgical intensive care unit of a university hospital. **Patients:** Forty mechanically ventilated patients with circulatory insufficiency in whom volume expansion was planned by attending physician. Exclusion criteria included spontaneous respiratory activity, 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.



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



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.

Masimo-supported Study

43 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.

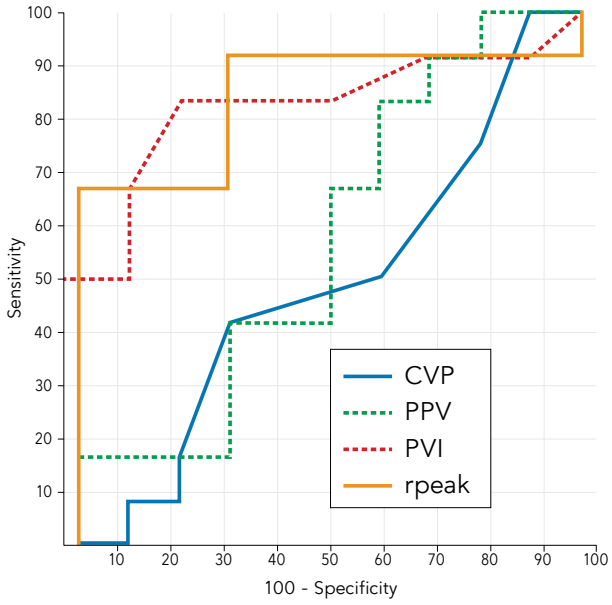
Methods

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



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.

44 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

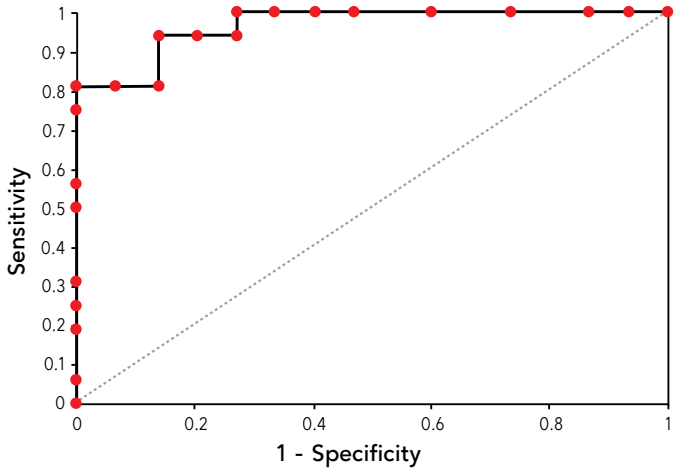
Monocentric, prospective, observational study that included 31 mechanically ventilated and sedated patients with septic shock in whom volume expansion was planned. The patients were equipped with a pulse oximeter that automatically calculated and displayed PVi. The intervention consisted in infusing 8 mL/kg of hydroxylethyl starch over a 20-minute period. Before and after intervention, we [study investigators] 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 [investigators'] study suggests that PVi is a feasible and interesting method to predict fluid responsiveness in early phase septic shock patients in the emergency department.



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

45 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 [study investigators] hypothesized that PVi could predict the hemodynamic effects of 10 cm H_2O positive end-expiratory pressure (PEEP).

Methods

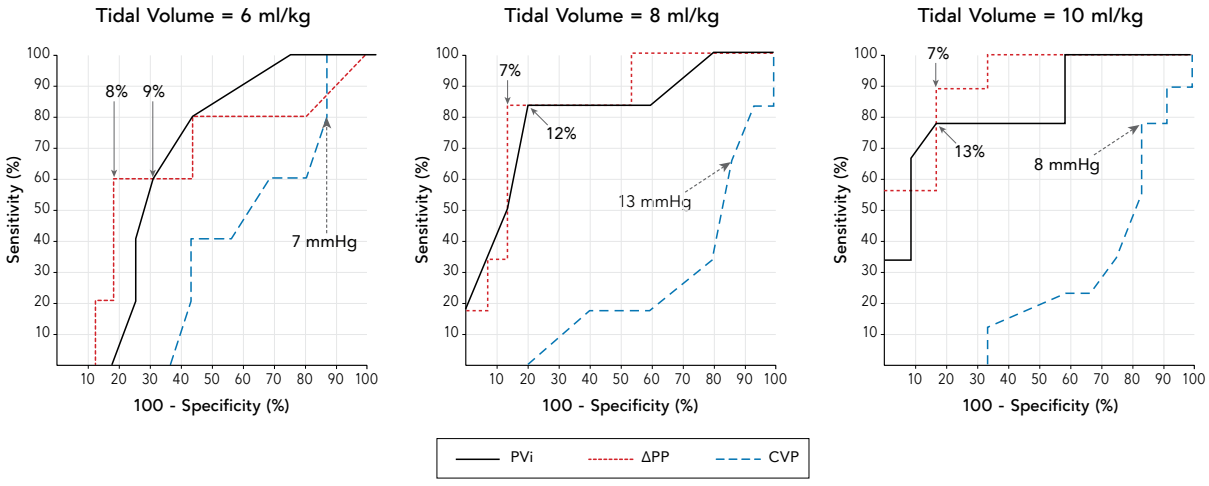
We [investigators] studied 21 mechanically ventilated and sedated patients in the postoperative period after coronary artery bypass grafting. Patients were monitored with a pulmonary artery catheter and a pulse oximeter sensor attached to the index finger. Hemodynamic data (cardiac index [CI], PVi, pulse 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.



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

46 Pleth Variability Index May Predict Preload Responsiveness in Patients Treated with Nasal High Flow: A Physiological Study

García-de-Acilu M, Pacheco A, Santafé M, Ramos FJ, Ruiz-Rodríguez JC, Ferrer R, Roca O. *J Appl Physiol* (1985). 2021 Jun 1;130(6):1660-1667.

The purpose of this study was to determine whether the plethysmographic variability index ("PVi") can predict preload responsiveness in patients with nasal high flow (NHF) (≥30 L/min) with any sign of hypoperfusion. "Preload responsiveness" was defined as a ≥10% increase in stroke volume (SV), measured by transthoracic echocardiography, after passive leg raising. SV and PVi were reassessed in preload responders after receiving a 250-mL fluid challenge. Twenty patients were included and 12 patients (60%) were preload responders. Responders showed higher baseline mean PVi (24% vs. 13%; P = 0.001) and higher mean PVi variation (ΔPVi) after passive leg raising (6.8% vs. -1.7%; P < 0.001). No differences between mean ΔPVi after passive leg raising and mean ΔPVi after fluid challenge were observed (6.8% vs. 7.4%; P = 0.24); and both values were strongly correlated (r = 0.84; P < 0.001). Baseline PVi and ΔPVi after passive leg raising showed excellent diagnostic accuracy identifying preload responders (AUROC 0.92 and 1.00, respectively). Baseline PVi ≥ 16% had a sensitivity of 91.7% and a specificity of 87.5% for detecting preload responders. Similarly, ΔPVi after passive leg raising ≥2% had a 100% of both sensitivity and specificity. Thus, PVi might predict "preload responsiveness" in patients treated with NHF, suggesting that it may guide fluid administration in these patients.

New & Noteworthy

This is the first study that analyzes the use of noninvasive plethysmographic variability index (PVi) for preload assessment in patients treated with nasal high flow (NHF). Its results showed that PVi might identify preload responders. Therefore, PVi may be used in the day-to-day clinical decision-making process in critically ill patients treated with NHF, helping to provide adequate resuscitation volume.

Diagnostic accuracy of the baseline PVi ≥16% and ΔPVi after passive leg raising ≥2% for predicting PR, defined as an increase of ≥10% in SV after PLR.

	Sensitivity	Specificity	PPV	NPV	LR^+	LR^-
Baseline PVi ≥ 16, %	91.7 (61.5-99.8)	87.5 (47.3-99.7)	91.7 (61.5-99.8)	87.5 (47.3-99.7)	7.33 (1.16-46.23)	0.10(0.01-0.63)
ΔPVi after PLR ≥ 2, %	100 (73.5-100)	100 (63.1-100)	100 (73.5-100)	100 (63.1-100)	NA	NA

Values are percentages (95% CI). LR, likelihood ratio; NPV, negative predictive value; PLR, passive leg raising; PPV, positive predictive value; PVi, pleth variability index.

47 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

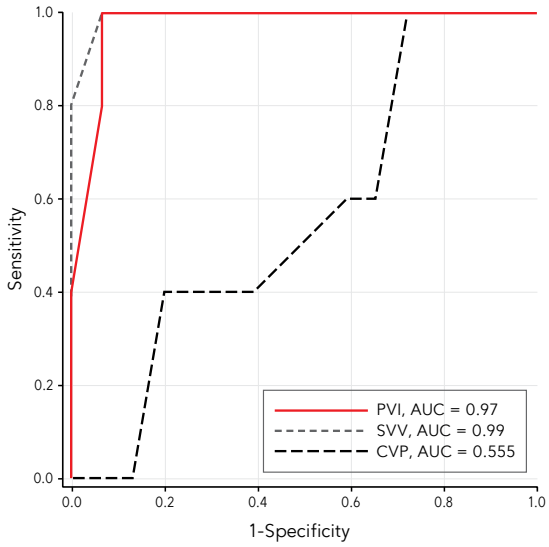
Accurate assessment of a patient's volume status is an important goal for an anesthetist. However, most variables assessing fluid responsiveness are either invasive or technically challenging. This study was designed to compare the accuracy of arterial pressure-based stroke volume variation (SVV) and 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

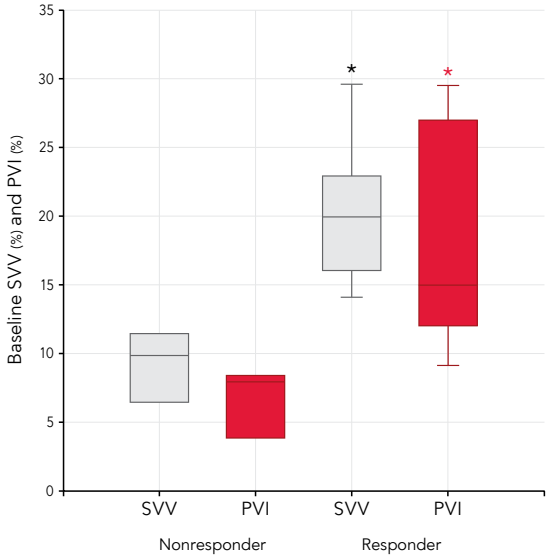
We [investigators] studied 20 patients scheduled for elective major abdominal surgery. After induction of anesthesia, all haemodynamic variables were recorded immediately before (T1) and subsequent to volume replacement (T2) by infusion of 6% hydroxyethyl starch (HES) 130/0.4 (7 mL kg) at a rate of 1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



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



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 [investigators'] study suggest that both variables, SVV and PVi, can serve as valid indicators of fluid responsiveness in mechanically ventilated patients undergoing major surgery.

48 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 [investigators'] prospective clinical study was to evaluate if volume responsiveness can be predicted by PVi in patients undergoing cardiac surgery after cardiopulmonary bypass.

Methods

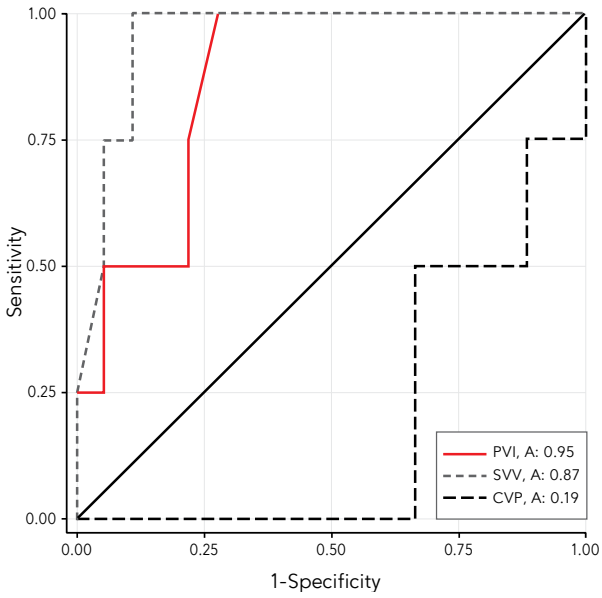
Eighteen patients were prospectively studied. Directly after cardiac surgery, PVi, stroke volume variation (SVV), and cardiac index (CI) were recorded. Colloid infusion(4 mL/kg body weight) was used for volume loading, and volume responsiveness was defined as increase of CI more than 10%.

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.

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.



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

49 Use of the Pleth Variability Index in Children with Obstructive Respiratory Disease

Demir G, Berksoy E, Bardak Ş, Elibol P, Çiçek A, Özön A, Nalbant T, Gökalp G. *Am J Emerg Med*. 2022. Epub 2022 Mar 17.

Introduction

The phenomenon of pulsus paradoxus (PP) develops at varying rates in relation to the severity of the disease in obstructive respiratory tract disease. The Pleth Variability Index (PVI) is the measurement value of perfusion index changes that occur with ventilation, which are determined during at least one respiratory cycle. Therefore, noninvasive measurement of PVI can help in the measurement of PP. The current study aims to determine the role of PVI measurements before and after bronchodilator therapy during admission to the hospital in children with obstructive respiratory tract disease.

Methods

Age, gender, Pulmonary Index Score (PIS), and PVI data of patients aged 2-18 years who applied to the pediatric emergency department with signs of obstructive respiratory tract disease were recorded in triage. The PVI and PIS scores of the patients, who were divided into three groups according to their clinical severity scores, were recorded before and after bronchodilator treatment, and they were compared to the PVI values according to the disposition results.

Results

A total of 133 patients were included in this prospective, single-center study. The PVI values before and after treatment were significantly higher in patients with severe disease compared to the mild and moderate groups ($p < 0.001$). Post-treatment PVI values were significantly lower than pre-treatment values in all clinical severity groups ($p < 0.001$). While a total of 95 (71.43%) patients were discharged from the emergency department, 31 (23.31%) patients were admitted to the relevant department, and seven (5.26%) patients were admitted to the pediatric intensive care unit. The PVI values before and after treatment were significantly higher in the hospitalized group compared to the group discharged from the emergency department ($p < 0.001$). The areas under the ROCs were 0.940, 0.865, and 0.843 for the PVI measurements in patients with severe disease, moderate disease, and hospitalization ($p< 0.001$).

Conclusions

Automated PVI measurement can be used as a noninvasive, rapid, and objective tool in the emergency department triage of patients admitted to the pediatric emergency department with signs of asthma attack or reactive respiratory tract disease.

Predictive performance of the PVI.

	Severe disease (*n* = 133)	Moderate & Severe disease (*n* = 133)	Hospitalization (*n* = 83)
Cut-off	>37.5	>28.5	>37.5
Sensitivity	100.00%	77.11%	91.89%
Specificity	85.00%	86.00%	71.74%
Accuracy	88.72%	80.45%	80.72%
PPV	68.75%	90.14%	72.34%
NPV	100.00%	69.35%	91.67%
AUC (95.0% CI)	0.940 (0.902-0.978)	0.865 (0.805-0.926)	0.843 (0.757-0.928)
P	<0.001	<0.001	<0.001

PPV: Positive Predictive Value, NPV: Negative Predictive Value
AUC: Area Under ROC Curve, CI: Confidence Intervals, PVI: Pleth Variability Index

50 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 [study investigators] speculated that pre-anesthesia PVi would be able to identify high-risk patients for significant blood pressure decrease during anesthesia induction.

Methods

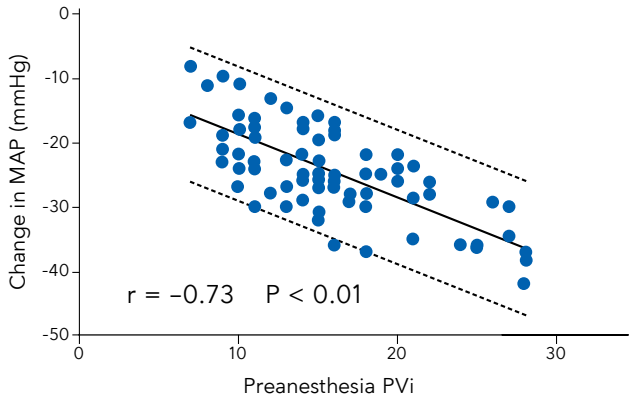
We [study investigators] measured the PVi, heart rate (HR), systolic blood pressure (SBP), diastolic blood pressure (DBP), and mean arterial pressure (MAP) in 76 adult healthy patients under light sedation with fentanyl to obtain pre-anesthesia control values. Anesthesia was induced with bolus administrations 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.



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

51 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

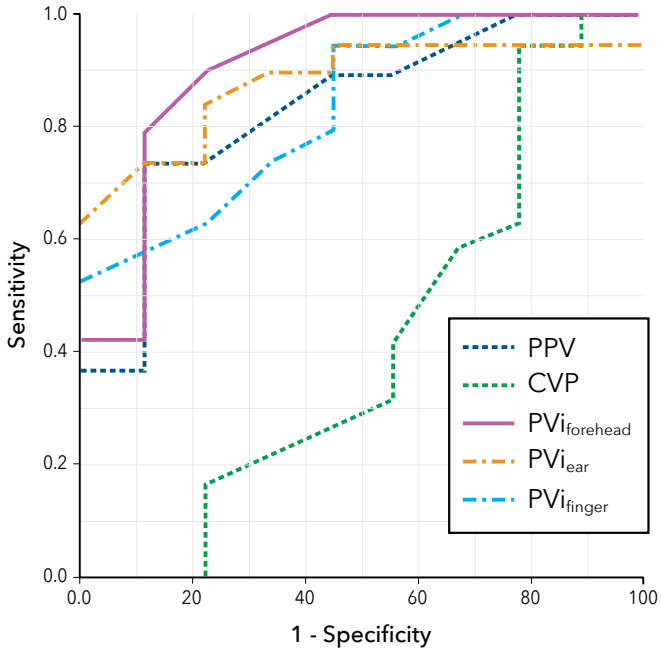
We [investigators] studied 28 subjects after induction of general anaesthesia. Subjects were monitored with a pulmonary artery catheter and three pulse oximeter sensors (the finger, ear, and forehead). Pulse pressure variation, central venous pressure, cardiac index (CI), and PVi measured at the forehead, 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.



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.

52 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

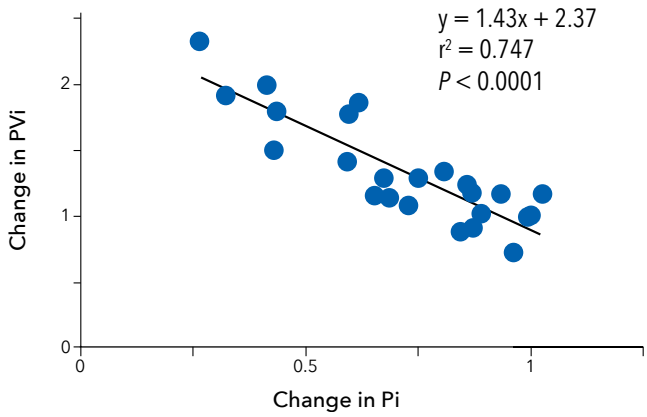
Twenty-four patients were examined after the induction of general anesthesia. Heart rate (HR), mean arterial blood pressure (MBP), Pi, PVi, stroke volume variation (SVV), and cardiac index (CI) were recorded before and after the skin incision. Pi and PVi were calculated using a Radical 7 pulse oximeter,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



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.

53 Performance of Automated Versus Nurse-measured Respiratory Rate Measurements in Hospitalised Malnourished Children

Dale NM, Parshuram C, Tomlinson G, Shepherd S, Mohammed Ashir G, Bukar LM, Zlotkin S. *Acta Paediatr*. 2021 Jul;110(7):2249-2251.

In resource limited settings accurate respiratory rate (RR) measurement directly informs medical decision making for children with respiratory problems. Counting RR remains a challenge: it may not be done or gives rise to highly disparate values despite the use of RR counters. Technological solutions may permit more children to have assessments and may alter clinical decisions. A hand-held pulse oximeter with integrated RR measurement (Rad-G, Masimo, Irvine California) in 97 children reported good agreement between measurements of the device and pediatricians. Our [investigators'] primary objective was to compare simultaneous RR measurements by device and nurse-measured manual count in a sample of malnourished hospitalized children. We [study investigators] also evaluated the potential clinical impact of changing approaches.

Automated (Rad G) vs manual nurse-measured respiratory rate measurements by age group and respiratory rate classification

Ages (months)	Paired Measurements N (%)	Mean Difference (95% CI)	Limits of Agreement (Mean difference ± 2 SD) with Upper and Lower 95% CI	ICC (95% CI)
6–59	6889 (100)	1.30 (1.16-1.44)	−10.34 to 12.94 L: −10.58 to −10.10 U: 12.70 to 13.18	0.84 (0.83 to 0.84)
6–11	2639 (38)	1.30 (1.06 to 1.54)	−11.28 to 13.88 L: −11.70 to −10.87 U: 13.46 to 14.29	0.80 (0.79 to 0.81)
12–59	4250 (62)	1.30 (1.14-1.47)	−9.71 to 12.32 L: −9.99 to −9.42 U: 12.03 to 12.61	0.85 (0.84 to 0.86)

	Paired Measurements N(%)	Kappa (95% CI)	Absolute Agreement
IMCI Respiratory Rate Threshold: 6–11 months **Manual count**			
≤ 50/Rad G count ≤ 50	1802 (68)	0.55 (0.52 to 0.59)	84%
≤ 50/Rad G count > 50	309 (12)		
> 50/Rad G count ≤ 50	119 (5)		
> 50/Rad G count > 50	409 (15)		
IMCI Respiratory Rate Threshold: 12–59 months **Manual count**			
≤ 40/Rad G count ≤ 40	1718 (40)	0.68 (0.65 to 0.70)	84%
≤ 40/Rad G > 40	544 (13)		
> 40/Rad G count ≤ 40	151 (4)		
> 40/Rad G count > 40	1837 (43)		
BedsidePEWS REspiratory Rate Category: 6–59 months (Rad G Rate – Manual Rate)			
−3 to −2 points	19 (0)	0.80 (0.79 to 0.81)	80%
−1 point	346 (5)		
0 points	5496 (80)		
1 point	1001 (15)		
2 to 3 points	27 (0)		

54 Measuring Accuracy of Plethysmography Based Respiratory Rate Measurement Using Pulse Oximeter at a Tertiary Hospital in India

Alwadhi V, Sarin E, Kumar P, Saboth P, Khera A, Gupta S, Kumar H. *Pneumonia* (Nathan). 2020 Jun 5;12:4.

Background

Childhood pneumonia continues to be a major infectious killer in India. WHO recommended respiratory rate and oxygen saturation (SpO_2) measurements are not well implemented in Indian public health outpatient facilities with the result that treatment decision-making rely on subjective assessments from variably trained and supervised healthcare providers. The introduction of a multi-modal pulse oximeter (POx) that gives reliable measurements would mitigate incorrect diagnosis. In light of future potential use of pulse oximeter in peripheral health centres, it becomes important to measure accuracy of respiratory rate and oxygen saturation of such an instrument. The current study measures accuracy of plethysmography based respiratory rate (RR) using a pulse oximeter (Masimo Rad-G) by comparing it with a gold standard (pediatrician) measurement.

Study Design

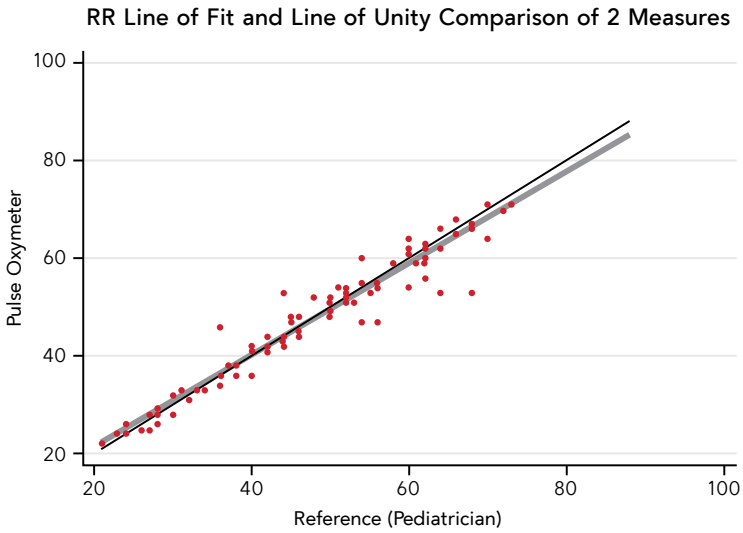
A cross sectional study was conducted in the OPD and emergency ward of Kalawati Saran Children's Hospital over a 2 week period wherein a convenience sample of 97 children (2 to 59 months) were assessed by a pediatrician as part of routine assessment alongside independent measure by a consultant using pulse oximeter. The level of agreement between plethymography based RR and pediatrician measure was analyzed along with sensitivity and specificity of fast breathing of plethymography based RR measure.

Results

Both methods of measurement show strong association (97%, $p < 0.001$) and observed values, falling on line of unity, obtained either from pulse oximeter or by pediatrician are very close to each other. Fast breathing measured by POx has a sensitivity of 95% and specificity of nearly 94%.

Conclusions

The current study provides evidence of the accuracy of a plethysmography based RR using a pulse oximeter which can potentially be of use in planning of pneumonia management in public health facilities.



Line of fit of RR values obtained from both the measurements

55 Inpatient Respiratory Arrest Associated With Sedative and Analgesic Medications: Impact of Continuous Monitoring on Patient Mortality and Severe Morbidity

McGrath SP, McGovern KM, Perreard IM, Huang V, Moss LB, Blike GT. *J Patient Saf*. 2021 Dec 1;17(8):557-561.

Objectives

The primary study objective was to investigate the impact of surveillance monitoring (i.e., continuous monitoring optimized for deterioration detection) on mortality and severe morbidity associated with administration of sedative/analgesic medications in the general care setting. A second objective was consideration of the results in the context of previous investigations to establish practice recommendations for this approach to patient safety.

Methods

Retrospective review of available rescue event and patient safety data from a tertiary care hospital in a rural setting was performed for a 10-year period. Systematic analysis of all adult general care inpatient data followed by chart review for individual patients was used to identify patient death or permanent harm (i.e., ventilator dependency, hypoxic encephalopathy) related to administration of sedative/analgesics.

Results

Of 111,488 patients in units with surveillance monitoring available, none died or were harmed by opioid-induced respiratory depression when surveillance monitoring was in use. One patient died from opioid-induced respiratory depression in a unit where surveillance monitoring was available; however, the patient was not monitored at the time of the adverse event. In unmonitored units (15,209 patients during 29 months of incremental implementation), three patients died from opioid overdose (19.73 deaths per 100,000 at risk patients). The reduced death rate when surveillance monitoring was available (0.0009%) versus not available (0.02%) was significant (P = 0.03).

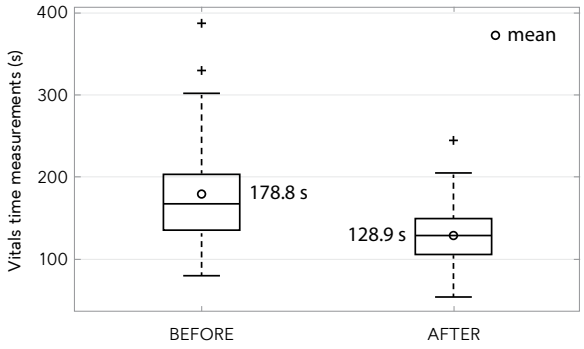
Conclusions

For a 10-year period, the rescue system with continuous surveillance monitoring had a profound effect on death from sedative/analgesic administration in the general care setting. This approach to patient safety can help address the risk of sedative/analgesic-related respiratory arrests in hospitals.

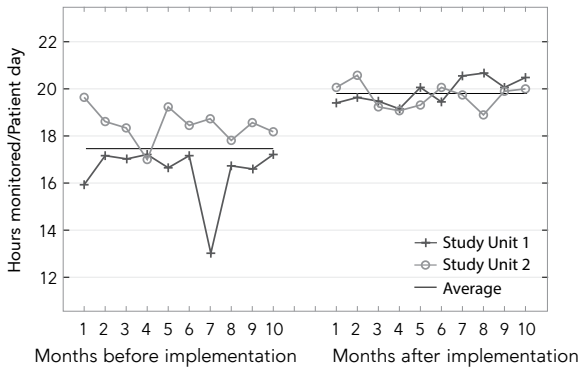
56 Improving Patient Safety and Clinician Workflow in the General Care Setting with Enhanced Surveillance Monitoring

McGrath S, Perreard I, Garland M, Converse K, and Mackenzie T. *IEEE J Biomed Health Infor*. 2019 Mar;23(2): 857-866.

Clinical monitoring systems have been implemented in the inpatient hospital setting for decades, with little attention given to systems analysis or assessment of impact on clinician workflow or patient care. This study provides an example of how system-level design and analysis can be applied in this domain, with specific focus on early detection of patient deterioration to mitigate failure to rescue events. Wireless patient sensors and pulse oximetry-based surveillance system monitors with advanced display and information systems capabilities were introduced to 71 general care beds in two units. Nursing workflow was redesigned to integrate use of the new system and its features into patient assessment activities. Patient characteristics, vital sign documentation, monitor alarm, workflow, and system utilization data were collected and analyzed for the period five months before and five months after implementation. Comparison unit data were also collected and analyzed for the same periods. A survey pertaining to staff satisfaction and system performance was administered after implementation. Statistical analysis was performed to examine differences in the before and after data for the target and control units. The enhanced monitoring system received high staff satisfaction ratings and significantly improved key clinical elements related to early recognition of changes in patient state, including reducing average vital signs data collection time by 28%, increasing patient monitoring time (rate ratio 1.22), and availability and accuracy of patient information. Impact on clinical alarms was mixed, with no significant increase in clinical alarms per monitored hour.



Box plot of vital signs collection time before and after implementation of the enhanced monitoring system. The mean difference of 50 seconds per patient translates to over 3 hours per day in a 36-bed unit.



Monitoring system utilization in study units before and after implementation. Monthly mean hours monitored per patient day shown for the period 10 months before and 10 months after implementation.

57 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

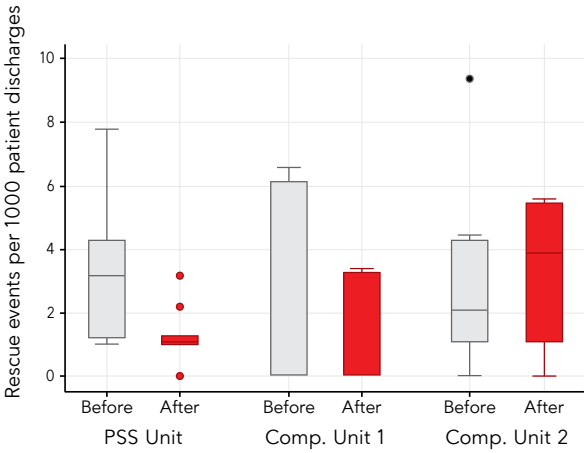
Some preventable deaths in hospitalized patients are due to unrecognized deterioration. There are no publications of studies that have instituted routine patient monitoring postoperatively and analyzed impact on patient outcomes.

Methods

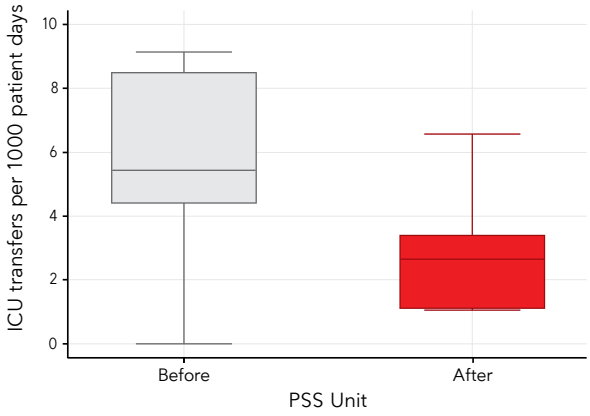
The authors implemented a patient surveillance system based on pulse oximetry with nursing notification of violation of alarm limits via wireless pager. Data were collected for 11 months before and 10 months after implementation of the system. Concurrently, matching outcome data were collected on 2 other 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.



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



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.

58 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.

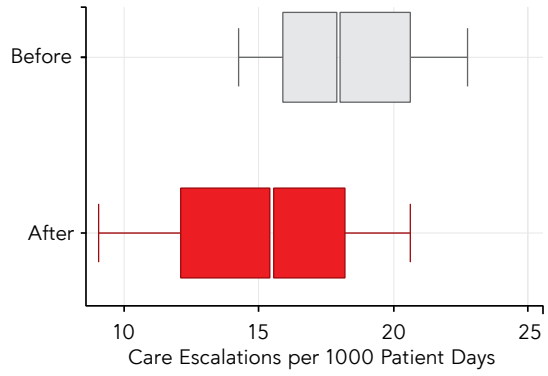
Methods

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.

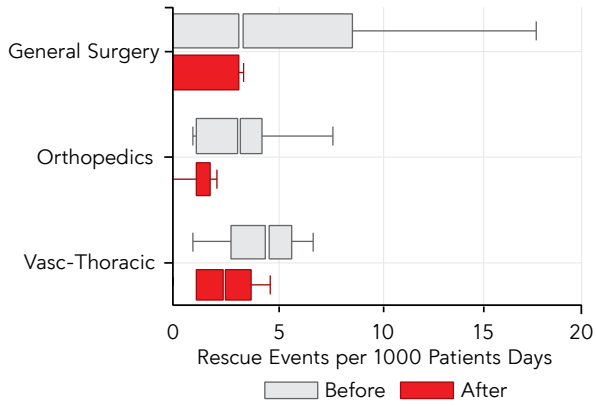
Result

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.



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



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.

59 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.

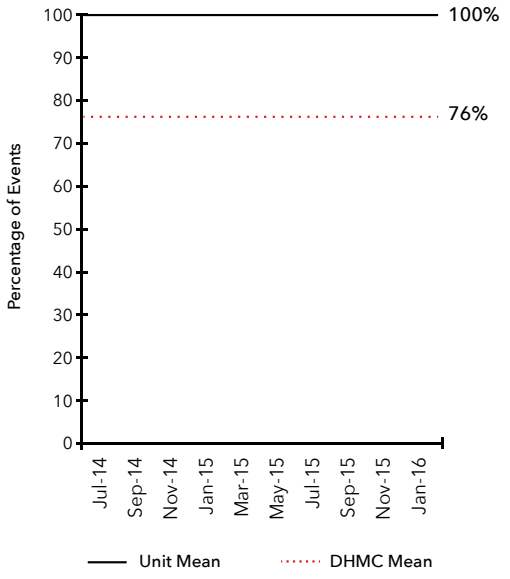
Results

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



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.

60 Patient SafetyNet for the Evaluation of Postoperative Respiratory Status by Nurses: A Presurvey and Postsurvey Study

Ishikawa M, Sakamoto A. *J Perianesth Nurs*. 2021 Feb;36(1):14-17.

Purpose

The purpose of this pre-post survey study was to assess the effect of the Patient SafetyNet system (Masimo Corp, Irvine, CA) on postoperative respiratory evaluation by nurses in general wards. Patient SafetyNet is a wireless monitoring system that evaluates respiratory rate and percutaneous oxygen saturation.

Design

Survey of nurses at a single medical center.

Methods

Staff nurses (n = 75) were queried using a questionnaire asking about methods and problems of postoperative respiratory monitoring, usefulness of this system, and suggestions about suitable cases of this system.

Findings

A total of 75 questionnaires were completed and returned. The nurses reported that central/remote (89.3%) or continuous (98.7%) monitoring was useful in the postquestionnaire. Moreover, the average frequency of clinical examination was reduced from 11.0 ± 2.3 to 5.1 ± 1.3. Using the Patient SafetyNet system led to a reported 61.3% reduction in nursing workload related to respiratory assessment postoperatively.

Conclusions

Continuous monitoring of respiratory rate and percutaneous oxygen saturation after general anesthesia is recommended for patients' safety. Moreover, Patient SafetyNet can decrease the number of physical assessments of respiratory status for postoperative patients in the general wards, resulting in reduction of nurse's workload.

Answers to Prequestions and Postquestions

Questions	Pre, *n* (%)	Post, *n* (%)	*P*
How many hours should you check the respiratory status of postoperative patients?			.819
1: <2 h	7 (9.3)	15 (20.0)	
2: 2 to 4 h	11 (14.7)	18 (24.0)	
3: 4 to 6 h	27 (36.0)	34 (45.3)	
4: more than 6 h	30 (40.0)	8 (10.7)	
Do you have any problems with respiratory status evaluation be the current method? (yes)	20 (26.7)	11 (14.7)	.149
Is a continuous monitoring of respiratory status useful? (yes)	66 (88.0)	74 (98.7)	NS
Is a remote monitoring of respiratory status useful? (yes)	59 (78.7)	67 (89.3)	.677

NS, not significant.

02: Pulse CO-Oximetry

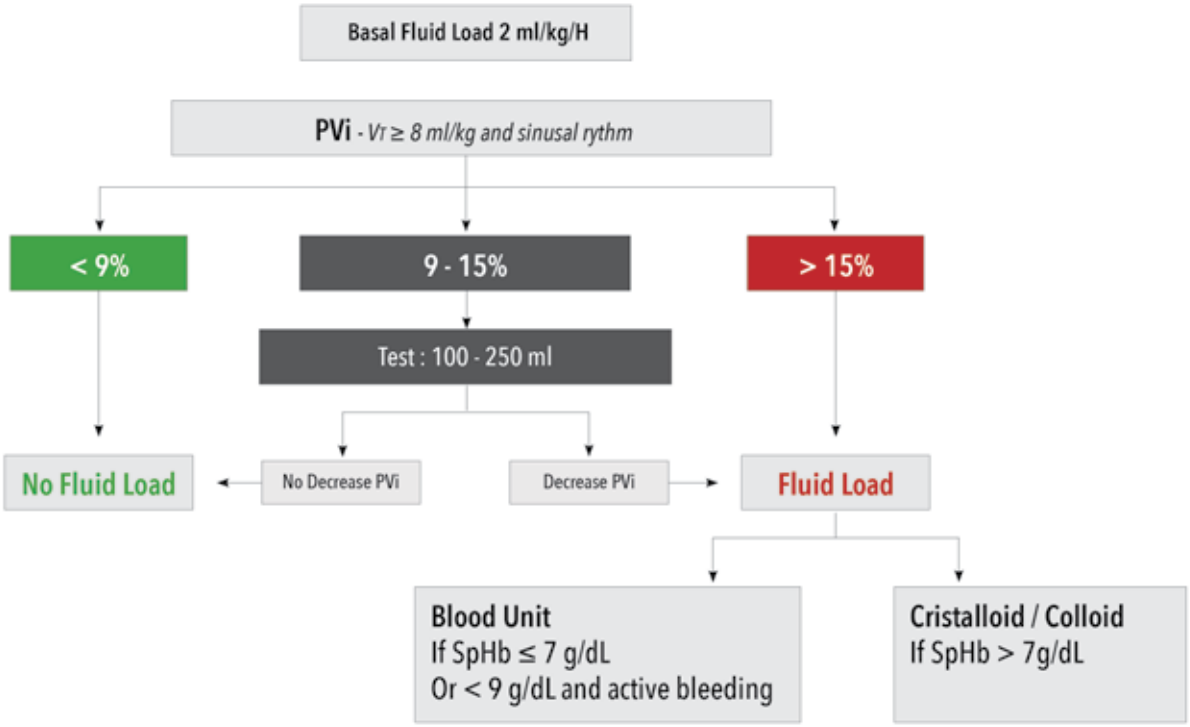
SpHb is not intended to replace laboratory blood testing. Blood samples should be analyzed by laboratory instruments prior to clinical decision making.

61 Continuous Hemoglobin and Plethysmography Variability Index Monitoring Can Modify Blood Transfusion Practice and is Associated With Lower Mortality

Cros, J., Dalmay, F., Yonnet, S. et al. *J Clin Monit Comput* 2019.

Abstract

To determine the effect of implementing an algorithm of fluid and blood administration based on continuous monitoring of hemoglobin (SpHb) and PVI (plethysmography variability index) on mortality and transfusion on a whole hospital scale. This single-center quality program compared transfusion at 48 h and mortality at 30 days and 90 days after surgery between two 11-month periods in 2013 and 2014 during which all the operating and recovery rooms and intensive care units were equipped with SpHb/PVI monitors. The entire team was trained to use monitors and the algorithm. Team members were free to decide whether or not to use devices. Each device was connected to an electronic wireless acquired database to anonymously acquire parameters on-line and identify patients who received the monitoring. All data were available from electronic files. Patients were divided in three groups; 2013 (G1, n = 9285), 2014 without (G2, n = 5856) and with (G3, n = 3575) goal-directed therapy. The influence of age, ASA class, severity and urgency of surgery and use of algorithm on mortality and blood use were analyzed with cox-proportional hazard models. Because in 2015, SpHb/PVI monitors were no longer available, we [study investigators] assessed post-study mortality observed in 2015 to measure the impact of team training to adjust vascular filling on a patient to patient basis. During non-cardiac surgery, blood was more often transfused during surgery in G3 patients as compared to G2 (66.6% vs. 50.7%, p < 0.001) but with fewer blood units per patient. After adjustment, survival analysis showed a lower risk of transfusion at 48 h in G3 [OR 0.79 (0.68–0.93), p = 0.004] but not in G2 [OR 0.90 (0.78–1.04) p = 0.17] as compared to G1. When adjusting to the severity of surgery as covariable, there was 0.5 and 0.7% differences of mortality at day 30 and 90 whether patients had goal directed therapy (GDT). After high risk surgery, the mortality at day 30 is reduced by 4% when using GDT, and 1% after intermediate risk surgery. There was no difference for low risk surgery. G3 Patients had a lower risk of death at 30 days post-surgery [OR 0.67 (0.49–0.92) p = 0.01] but not G2 patients [OR 1.01, (0.78–1.29), p = 0.96]. In 2015, mortality at 30 days and 90 days increased again to similar levels as those of 2013, respectively 2.18 and 3.09%. Monitoring SpHb and PVI integrated in a vascular filling algorithm is associated with earlier transfusion and reduced 30 and 90-day mortality on a whole hospital scale.

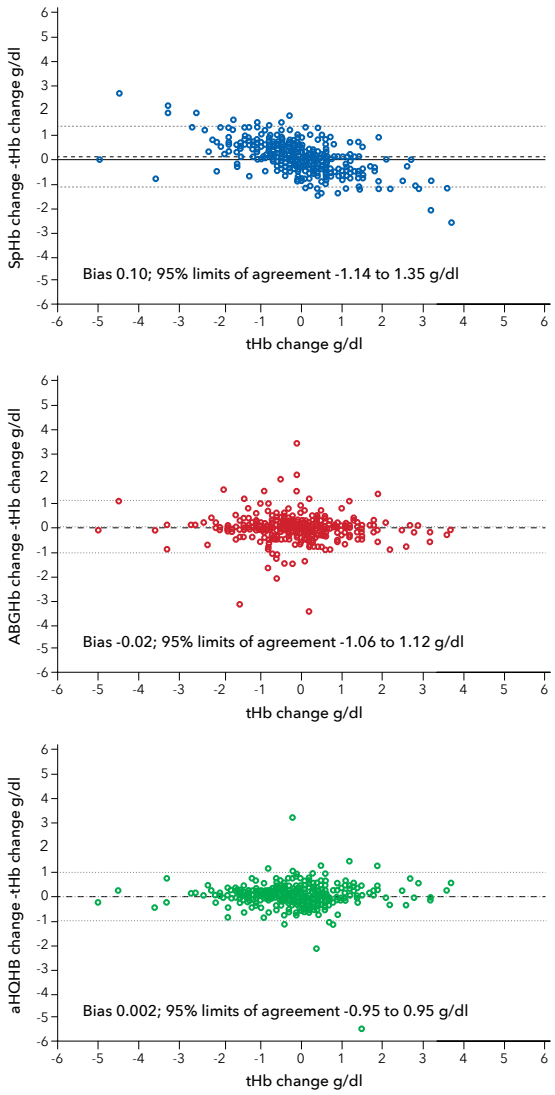


Algorithm of blood transfusion and fluid management according to results of SpHb and pulse pressure variation.

62 Multicenter Comparison of Three Intraoperative Hemoglobin Trend Monitoring Methods

Applegate R, Applegate P, Cannesson M, Peiris P, Ladlie B, Torp K. *J Clin Monit Comput*. 2019.

Transfusion decisions are guided by clinical factors and measured hemoglobin (Hb). Time required for blood sampling and analysis may cause Hb measurement to lag clinical conditions, thus continuous intraoperative Hb trend monitoring may provide useful information. This multicenter study was designed to compare three methods of determining intraoperative Hb changes (trend accuracy) to laboratory determined Hb changes. Adult surgical patients with planned arterial catheterization were studied. With each blood gas analysis performed, pulse cooximetry hemoglobin (SpHb) was recorded, and arterial blood Hb was measured by hematology (tHb), arterial blood gas cooximetry (ABGHb), and point of care (aHQHb) analyzers. Hb change was calculated and trend accuracy assessed by modified Bland-Altman analysis. Secondary measures included Hb measurement change direction agreement. Trend accuracy mean bias (95% limits of agreement; g/dl) for SpHb was 0.10 (- 1.14 to 1.35); for ABGHb was - 0.02 (- 1.06 to 1.02); and for aHQHb was 0.003 (- 0.95 to 0.95). Changes more than ± 0.5 g/dl agreed with tHb changes more than ± 0.25 g/dl in 94.2% (88.9-97.0%) SpHb changes, 98.9% (96.1-99.7%) ABGHb changes and 99.0% (96.4-99.7%) aHQHb changes. Sequential changes in SpHb, ABGHb and aHQHb exceeding ± 0.5 g/dl have similar agreement to the direction but not necessarily the magnitude of sequential tHb change. While Hb blood tests should continue to be used to inform transfusion decisions, intraoperative continuous noninvasive SpHb decreases more than - 0.5 g/dl could be a good indicator of the need to measure tHb.



Modified Bland-Altman analysis of trend accuracy comparing 416 sequential changes in laboratory hematology analyzer hemoglobin (tHb) to the difference between tHb changes and paired sequential changes in top panel: pulse cooximetry hemoglobin (SpHb); middle panel: arterial blood gas cooximetry hemoglobin (ABGHb) and bottom panel: Hemocue point of care hemoglobin using arterial blood (aHQHb). Horizontal dotted lines indicate 95% limits of agreement (± 1.96 SD).

63 Postoperative Patient Blood Management: Transfusion Appropriateness in Cancer Patients

Merolle L, Marraccini C, Di Bartolomeo E, Montella MM, Pertinhez TA, Baricchi R, Bonini A. *Blood Transfus*. 2020; 18: 359-65.

Background

While patient blood management (PBM) principles are not specific to cancer patients, their application contains the pathophysiological premises that could also benefit this patient population. In this study, we [investigators] assessed the effects of implementing a PBM bundle for cancer patients in the postoperative period.

Materials and Methods

The Azienda USL-IRCCS of Reggio Emilia implemented a two-step PBM bundle for the postoperative period of cancer patients hospitalised in the semi-intensive postoperative (SIPO) ward. Step 1 included seminars and lessons specifically targeting SIPO personnel; Step 2 introduced Points of Care (POCs) for the continuous monitoring of haemoglobin (Radical7, Masimo Corp, Irvine, CA, USA). We [study investigators] conducted 3 audits on 600 cancer patients recruited between 2014 and 2017: Audit 1 on 200 patients before the application of our [investigators'] PBM bundle; Audit 2 after Step 1 on 200 patients; Audit 3 after Step 2 on 200 patients monitored with POCs. Red blood cell (RBC) transfusion appropriateness in the postoperative period was evaluated using the Italian Society of Transfusion Medicine and Immunohaematology (SIMTI) recommendations.

Results

RBC transfusion appropriateness in the postoperative period of cancer patients rose from 38% to 75% after seminars, and reached 79% after the introduction of POC. The mean number of RBC units each patient received remained unchanged after training sessions (1.8 units/patient) while the introduction of POCs saw a simultaneous decrease in the number of prescribed units (1.3 units/patient).

Discussion

Our [investigators'] PBM bundle positively impacted RBC transfusion appropriateness in postsurgical cancer patients, both in terms of quality and quantity. A structured PBM programme specifically dedicated to surgical oncology should cover the entire perioperative period and might further improve transfusion appropriateness in these patients. The publication of guidelines on the management of anaemia in surgical oncology should be a priority.

Fig. A

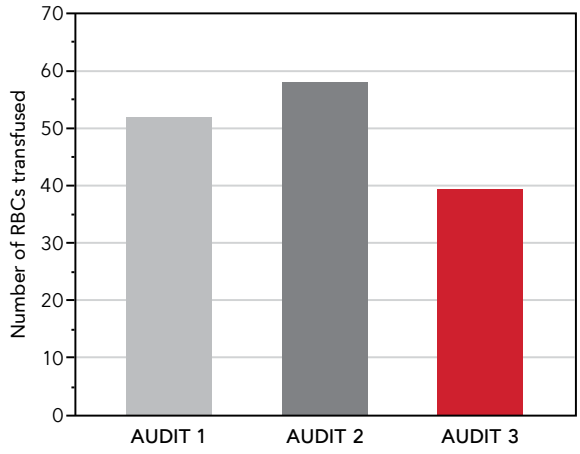
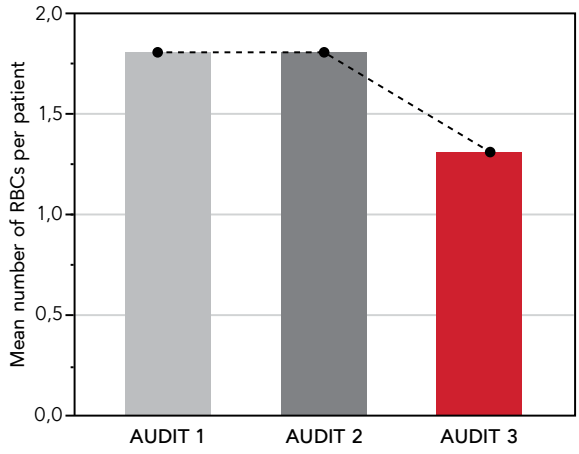


Fig. B



Red blood cell (RBC) units transfused in the postoperative period (A) Total number of transfused RBC units; (B) mean number of RBC units received by each patient.

64 Intraoperative and postoperative outcomes among the Standard Care Group (control) and SpHb Group (intervention).

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 [study investigators] 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.

Intraoperative and postoperative outcomes among the Standard Care Group (control) and SpHb Group (intervention).

	SpHb group (*N*=157)		Standard Care Group (*N*=157)		Differences	95% CI
Intraoperative		Total*		Total*		
Received 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.

65 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*

66 Postoperative Noninvasive Hemoglobin Monitoring Is Useful to Prevent Unnoticed Postoperative Anemia and Inappropriate Blood Transfusion in Patients Undergoing Total Hip or Knee Arthroplasty: A Randomized Controlled Trial

Nakamori E, Shigematsu K, Higashi M, Yamaura K. *Geriatr Orthop Surg Rehabil*. 2021 Nov 19;12:21514593211060575.

Introduction

Postoperative nadir hemoglobin (Hb) is related to a longer length of stay for geriatric patients undergoing orthopedic surgery. We [study researchers] investigated whether postoperative pulse Hb (SpHb) measurement is useful for avoiding anemia and inappropriate blood transfusion after total hip arthroplasty and total knee arthroplasty.

Material and Methods

This prospective randomized controlled study included 150 patients randomly assigned to receive blood transfusion, either guided by SpHb monitoring (SpHb group) or based on the surgeons' experience (control group). The target laboratory Hb value was set to >8 g/dL at postoperative day 1 (POD1). The primary endpoints were the product of total time and degree of SpHb <8 g/dL (area under SpHb 8 g/dL) during the period up to POD1 and the incidence of laboratory Hb <8 g/dL at POD1. The secondary endpoints were the amount of blood transfusion and inappropriate blood transfusion, which was defined as allogeneic blood transfusion unnecessary in a case of SpHb >12 g/dL or delayed transfusion in a case of SpHb <8 g/dL.

Results

The area under SpHb 8 g/dL was 37.6 ± 44.1 g/dL-min (5 patients) in the control group and none in the SpHb group (P = .0281). There was 1 patient with Hb <8 g/dL at POD1 in the control group. There was no difference in laboratory Hb levels and the amount of blood transfusion. Forty-one patients (19 in the control group and 22 in the SpHb group) received an allogeneic blood transfusion. Among these patients, 7 in the control group and none in the SpHb group received inappropriate blood transfusion (P = .0022).

Discussion

The SpHb monitoring could reduce unnoticed anemia, which may prevent complications and be useful in avoiding unnecessary and excessive blood transfusion.

Conclusion

Postoperative SpHb monitoring decreased the incidence of transient, unnoticed anemia during the period up to POD1 and inappropriate blood transfusion.

POD Mean Hb and Minimum Hb Level up to POD7.

		Control group (n = 72)	SpHb group (n = 73)	*P* value[a]
POD1	Mean Hb (g/dL) Minimum Hb (g/dL)	10.7 ± 1.3 (n = 72) 7.7	10.8 ± 1.2 (n = 73) 8.5	0.60
POD2	Mean Hb (g/dL) Minimum Hb (g/dL)	9.1 ± 1.3 (n = 10) 6.2	9.0 ± 1.8 (n = 9) 7.4	0.95
POD3	Mean Hb (g/dL) Minimum Hb (g/dL)	10.3 ± 1.3 (n = 31) 7.7	10.0 ± 1.1 (n = 26) 8.1	0.81
POD4	Mean Hb (g/dL) Minimum Hb (g/dL)	9.8 ± 1.3 (n = 36) 6.3	10.3 ± 1.8 (n = 29) 8.6	0.24
POD5	Mean Hb (g/dL) Minimum Hb (g/dL)	9.3 ± 1.8 (n = 6) 7.1	9.5 ± 1.5 (n = 5) 8	0.84
POD6	Mean Hb (g/dL) Minimum Hb (g/dL)	9.9 ± 1.3 (n = 12) 7.6	9.8 ± 1.0 (n = 11) 8.2	0.71
POD7	Mean Hb (g/dL) Minimum Hb (g/dL)	10.1 ± 1.1 (n = 44) 7.9	10.1 ± 1.1 (n = 46) 8.1	0.78

Data are presented as mean ± standard deviation or number (n). POD, postoperative day; Hb, hemoglobin.
[a]Derived using Student's *t*-test and/or chi-square test, $P < .05$ was considered to indicate statistical significance.

67 Monitoring of Plethysmography Variability Index and Total Hemoglobin Levels During Cesarean Sections with Antepartum Hemorrhage For Early Detection of Bleeding

Ahmed Elsakka, Wael Hossam, Gehan Helmy, Nadia Helmy. *Egyptian J Anaesthes*. 2017;33(1): 5-8

Background

Cesarean sections for parturients with antepartum hemorrhage have the potential risk of massive blood loss. In the current study we [study researchers] investigated the use of Plethysmography variability index (PVI) and non invasive hemoglobin (SPHB) monitoring as well for intraoperative detection of blood loss and intravascular volume status.

Methods

One hundred and twenty four full term parturients scheduled for elective CS were included in the study. All patients received general anesthesia after preoxygenation for 5 min, rapid-sequence induction performed with thiopental 3–5 mg/kg and suxamethonium 1.5 mg/kg; Anesthesia was maintained with a 100% of oxygen with 0.5–1 MAC of isoflurane and atracurium 0.5 mg/kg. Standard monitors (pulse oximetry, non-invasive blood pressure, and ECG) were applied. Masimo sensor was applied following best practice guidelines, and automated data collection (ADC) was done. Our [investigators'] primary outcome was to compare PVI values before versus after administration of fluids and blood that was given based on clinical data. Our [investigators'] secondary outcome was to review of SPHb traces plots to determine if and when SpHb may have detected presence of anemic state or critical drop in hemoglobin level when compared to time of clinical awareness of bleeding and confirmation by lab Hb sample measurement.

Results

PVI showed a significant negative correlation with CVP ($p = 0.037$) and a significant negative correlation with MAP ($p = 0.01$). Also, it showed significant positive correlation with HR ($p < 0.001$). A highly significant Correlation was found between pre transfusion lab Hb and pre transfusion SpHb ($p < 0.001$). Also post transfusion values showed a highly significant correlation as well ($p < 0.001$). A total of 87 transfusions (91.58%) were found unnecessary when using SpHb as the reference, compared to 58 (61.05%) when using the invasive laboratory measurement.

Conclusion

Plethysmography variability index and non invasive hemoglobin monitoring as well can be used for optimization of intravascular volume status during cesarean sections in parturients with antepartum hemorrhage.

Fig. 1

Fig. 2

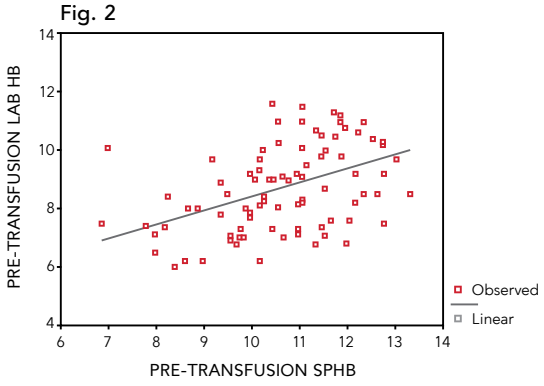


Fig. 3

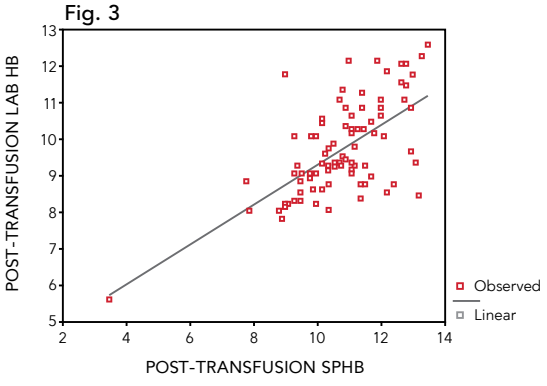


Figure 1. Linear regression curve showing significant positive correlation between PVI & HR (heart rate).

Figure 2. Linear regression curve showing significant positive correlation between pre transfusion lab HB and pre transfusion SpHB.

Figure 3. Linear regression curve showing significant positive correlation between post transfusion lab HB and post transfusion SpHB.

68

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)	12.4 +/- 1.6	11.5 +/- 1.0	0.02
Patients transfused, %	49	42	0.61
Pretransfusion Hb (g/dL)	8.3 ± 1.2	8.6 +/- 1.3	0.23
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 +/- 7.9	9.2 +/- 1.7	**<0.001**

69 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

70 Continuous Hemoglobin Measurement During Frontal Advancement Operations Can Improve Patient Outcomes

Saracoglu A, Abdullayev R, Sakar M, Sacak B, Girgin Incekoy F, Aykac Z. *J Clin Monit Comput*. 2022 Mar 7.

Massive hemorrhage in pediatric cranioplasty operations may necessitate blood transfusion, which may cause many complications. Radical-7 Pulse CO-Oximeter (Massimo Corporation, Irvine, CA) can provide continuous hemoglobin concentration (SpHb) measurements noninvasively. In this study, we [investigators] aimed to evaluate the effects of SpHb measurement on perioperative transfusion management and postoperative patient outcomes. For this retrospective case-control study, we [study investigators] collected the data of pediatric patients undergoing fronto-orbital advancement surgery for plagiocephaly and trigonocephaly between 2018 and 2021. Perioperative SpHb monitoring was performed for patients in the SpHb Group. Other patients that were managed conventionally were considered as the control group (C Group). The data on patients' demographic and clinical characteristics, intraoperative hemodynamic and laboratory variables such as blood gases, intraoperative blood losses, the amount of the transfused blood products, the length of postoperative intensive care unit (ICU) stay, and the duration of hospital stay were collected. The data of 42 patients were collected, and 29 of these patients were males (69%). In 16 of the patients, SpHb monitoring was performed. The demographic, clinical, and perioperative hemodynamic characteristics of the patients were comparable between the groups. Compared to the C Group, the SpHb Group had significantly lower perioperative packed red blood cell (PRBC) transfusion (136.3 ± 40.1 vs. 181.5 ± 74.8 mL, P = 0.015), less postoperative drainage (125.3 ± 47.7 vs. 185.8 ± 97.6 mL, P = 0.013), and shorter ICU stay (37.1 ± 12.0 vs. 64.8 ± 24.9 h, P < 0.001). There was a positive correlation between the amount of PRBC transfusion and the length of ICU stay (r = 0.459, P = 0.003). Patients with perioperative continuous SpHb measurement have lower intraoperative PRBC transfusion, less postoperative bleeding, and shorter ICU stay. When necessary, SpHb, together with clinical judgment and laboratory confirmation, can be used in decision-making for perioperative PRBC transfusion.

Perioperative clinical characteristics of the patients

	C Group (n=26)	SpHb Group (n=16)	P
Crystalloid (mL)	458.8 ± 156.2	479.4 ± 133.4	0.380
Colloid (mL)	22.3 ± 39.1	50.0 ± 44.0	0.025*
PRBC tx (mL)	181.5 ± 74.8	136.3 ± 40.1	0.015*
IO hemorrhage (mL)	192.7 ± 106.8	164.4 ± 51.8	0.540
IO urination (mL)	56.0 ± 47.1	54.0 ± 42.2	0.959
PO drainage (mL)	185.8 ± 97.6	125.3 ± 47.7	0.013*
ICU length of stay (hours)	64.8 ± 24.9	37.1 ± 12.0	<0.001*

Data is expressed as mean ± SD

C Group control group; *SpHb Group* group with SpHb measurement: *HRO/HR$_{End}$* mean arterial pressure at the start and the end of the operation; *MAP$_0$/MAP$_{End}$* mean arterial pressure at the start and the end of the operation; *T$_0$/T$_{End}$* body temperature at the start and the end of the operation; *PRBC tx* packed red blood cell transfusions; *IO* intraoperative; *PO* postoperative

*P<0.05

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Delay in Detection and Treatment of Perioperative Anemia in Hip Fracture Surgery and Its Impact On Postoperative Outcomes

Clemmesen CG, Palm H, Foss NB. *Injury*. 2019 Nov;50(11):2034-2039.

Background

Elderly patients with hip fractures are at high risk for perioperative anemia as a result of fracture- and surgery-related blood loss. The detection of anemia is dependent on intermittent blood samples and therefore might be delayed, potentially leading to a significant delay in transfusion. This study aimed to investigate the possible delay in perioperative anemia detection, accumulated perioperative anemia-associated burden, peripheral perfusion, and their association with patient outcomes in elderly patients with hip fracture.

Methods

Elderly patients with acute hip fracture scheduled for surgery were enrolled in this prospective study from August 2016 to December 2016. All patients were monitored continuously for hemoglobin concentration (SpHb) and perfusion index (PI) with the Radical-71 Pulse CO-Oximeter1 and Rainbow1 R1 Adhesive Multi-parameter Sensors (Masimo Corp., Irvine, CA, US) from 12 h presurgery to 24 h postsurgery.

Results

Fifty-one patients were enrolled, and 41 were included in the final analyses. Mean delay in the detection of low Hb (<10 g/dL) using intermittent blood samples, when compared with SpHb, was 1.07 h (standard deviation, 2.84 h). Median perioperative cumulated time with low SpHb (<10 g/dL for at least one min) was 25 min (interquartile range [IQR]: 21–690). There was a significant association between perioperative time with low SpHb and the occurrence of postoperative delirium (median cumulated time with low SpHb: 162 min in patients with delirium vs 22 min in patients without delirium, P = 0.034) and a nonsignificant trend for an association between perioperative time with low SpHb and 90-day mortality or medical complications (median cumulated time with low SpHb: 119 min for patients with mortality or severe complication vs 22 min for patients without mortality or severe complication, P = 0.104). PI values during the perioperative period were not significantly associated with patient outcomes. Cumulated time with low PI (<0.5) preoperatively (but not perioperatively) was significantly associated with the occurrence of postoperative delirium (P = 0.047).

Conclusions

This study showed a delay in transfusion threshold detection, and the presence of significant associations between low SpHb or time with low SpHb and postoperative outcomes.

	All patients (N = 42)	Delir = yes (N = 16)	Delir = no (N = 26)	P value	Dead at 90 days or severe complications (n = 15)	Alive at 90 days and no severe complications (n = 27)	P value
PHb							
Admission low pHb**	3	2	1	0.547	1	2	1.000
Low pHb at some point*	25	12	14	0.197	9	17	0.850
SpHb							
Event of low SpHb during surgery*	24 (57%)	12 (75%)	12 (50%)	0.067	11 (73%)	13 (48%)	0.193
Event of low SpHb pre, intra or post**	35 (83%)	16 (100%)	19 (73%)	0.033	14 (93%)	21 (78%)	0.390
Time with low SpHb							
Cumulated median (IQR) time with low SpHb***	49 (8–419)	162(30–819)	22 (4–137)	0.034	119 (49–325)	22 (4–514)	0.104
During surgery median (IQR) time with low SpHb***	8 (0–55)	21 (1–82)	0 (0–26)	0.113	20 (0–70)	0 (0–51)	0.146

** Chi-square. ** Fisher's exact. *** Non-parametric MannW.*

M Masimo-supported Study

72 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.

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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.

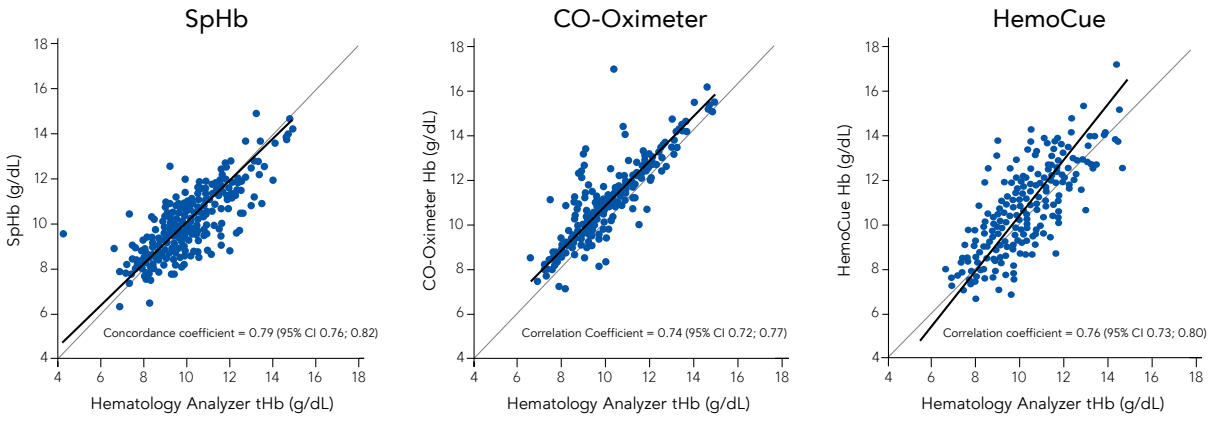
Methods

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

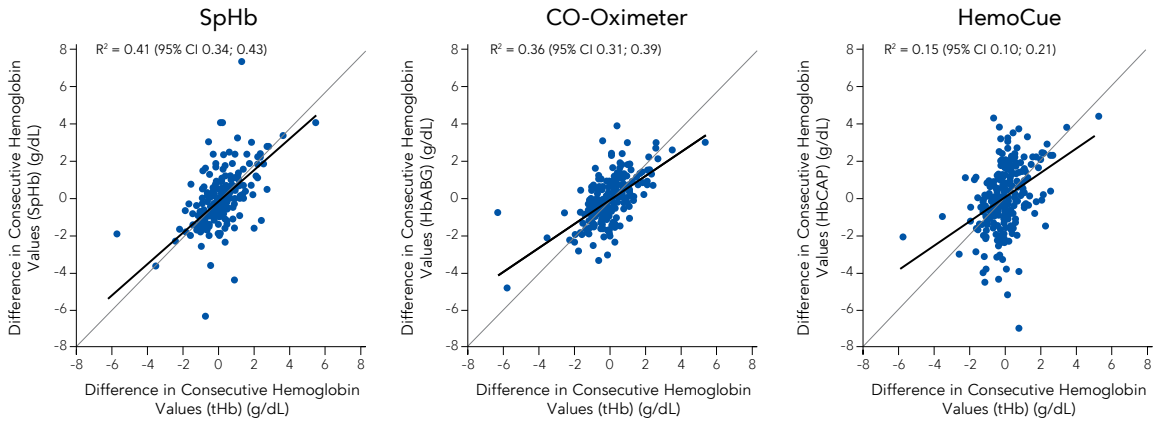
Four hundred seventy-one blood samples were analyzed by a point-of-care device (HemoCue 301), a satellite lab CO-oximeter (Siemens RapidPoint 405), and a laboratory hematology analyzer (Sysmex XT-2000i), which was considered the reference device. Hemoglobin values reported from the invasive methods were 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.

74 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

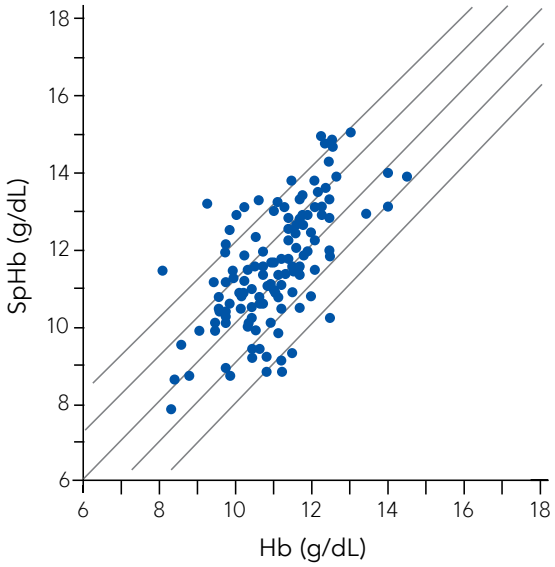
Rainbow Pulse CO-Oximetry technology (Masimo Corporation, Irvine, CA) provides continuous and noninvasive measurement of arterial hemoglobin concentration (SpHb). We [study investigators] assessed the trending and accuracy of SpHb by this innovative monitoring compared with Hb concentration obtained 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

75 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 [study investigators] 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

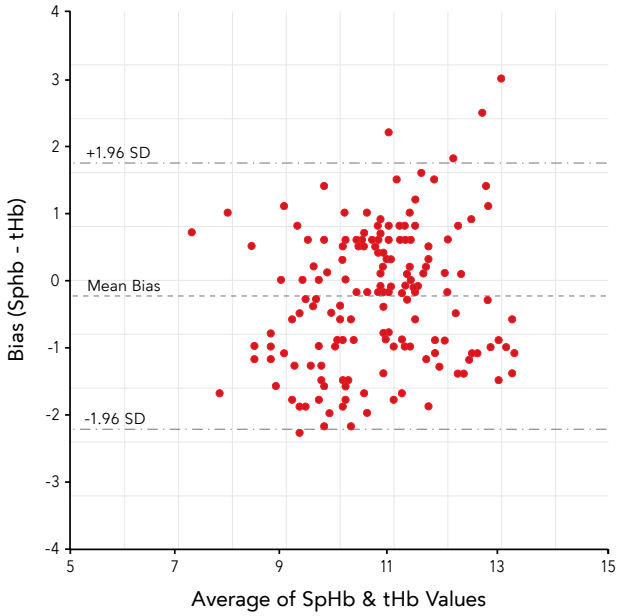
Patients eligible for the study were undergoing complex spine surgery with planned invasive arterial or central venous monitoring and hourly blood draws for hemoglobin measurement. During each surgery, blood samples were obtained hourly (or more often if clinically indicated) and analyzed by the central 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.



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

Masimo-supported Study

76 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 and SpHb 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.

77 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

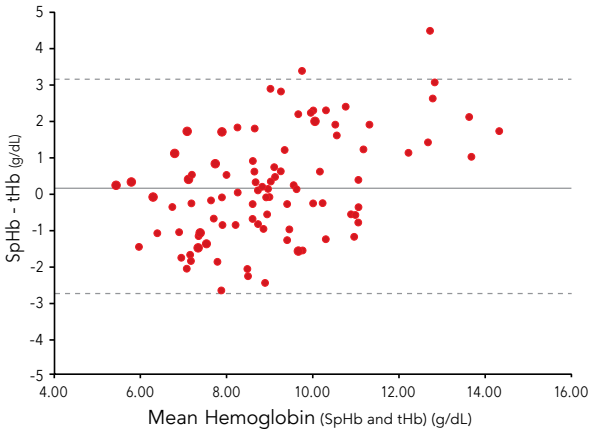
We [study investigators] evaluated the accuracy of noninvasive and continuous total hemoglobin (SpHb) monitoring with the Radical-7 Pulse CO-Oximeter in Japanese surgical patients before and after an in vivo adjustment of the first SpHb value to match the first reference value from a satellite laboratory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

Methods

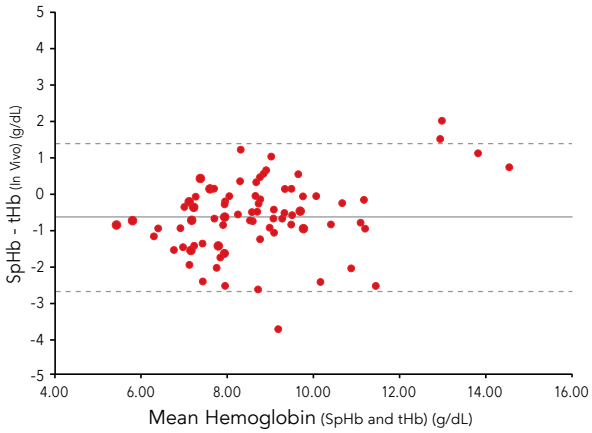
Twenty patients undergoing surgical procedures with general anesthesia were monitored with Pulse CO-Oximetry for SpHb. Laboratory CO-Oximeter values (tHb) were compared to SpHb at the time of the blood draws. Bias, precision, limits of agreement, and correlation coefficient of SpHb compared to tHb were 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.



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



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

Conclusion

In vivo adjustment of SpHb significantly improved the accuracy in our [investigators'] 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.

78 The Relationship Between Smoking Dependence, Exposure to Cigarette Smoke, Carboxyhemoglobin and Perioperative Complications in Patients Who Underwent Laparoscopic Cholecystectomy Under General Anesthesia

Eminoğlu Ş, Özgünay ŞE. *Eur Res J*. 2022;8(2):304-311.

Objectives

The aim of this study; to determine the effects of preoperative smoking dependence and noninvasively measured carboxyhemoglobin (COHb) levels on perioperative complications in patients who underwent elective laparoscopic cholecystectomy.

Methods

Ninety patients (Group I: smoker, Group II: non-smoker, and Group III: passive smoker) who underwent laparoscopic cholecystectomy under general anesthesia were studied. The level of dependence of smokers was evaluated with the Fagerstrom Test for Nicotine Dependence (FNBT). Preoperative COHb level was determined with a pulse CO-oximeter by placing a sensor on the fingertip. Respiratory complications in the perioperative and recovery room and Modified Aldrete Score (MAS) in the recovery room were recorded as 5th, 10th and 15th min.

Results

Female gender was significantly higher in Groups II and III. Significant increases were noted in Group I in terms of increased perioperative secretion and incidence of bronchospasm. In the recovery room, the increase in MAS 5th min in Group I and MAS 10th min and 15th min in Group III was significantly lower. In Group I, positive correlations between the COHb level and the number of cigarettes smoked and the FNBT level, and a negative correlation between MAS and the number of hours past after the last cigarette smoked were determined. In Group II, the COHb level correlated positively with the number of cigarette smokers at home and negatively with MAS. All these correlations were statistically significant.

Conclusion

It was demonstrated that cigarette smoking increased the incidence of perioperative respiratory complications under general anesthesia. Preoperative COHb level estimated by the pulse CO-oximeter can be used as an indicant of the potential risk of perioperative respiratory complications.

Demographic data

	Group I (n = 30)	Group II (n = 30)	Group III (n = 30)	*p* value
Age (years), (mean ± SD)	50.10 ± 10.32	49.53 ± 16.04	47.27 ± 12.17	0.625
Gender, n (%)				**<0.001**
Female	13 (43.3)	26 (86.7)	27 (90.0)	
Male	17 (56.7)	4 (13.3)	3 (10.0)	
ASA, n (%)				0.158
I	2 (6.7)	8 (26.7)	8 (26.79)	
II	26 (86.7)	21 (70)	22 (73.3)	
III	2 (6.7)	1 (3.3)	0 (0.0)	
Comorbidities, n (%)				0.731
Yes	16 (53.3)	15 (50.0)	18 (60,0)	
No	14 (46.7)	15 (50.0)	12 (40.0)	
COHb level (%), (mean ± SD)	3.23 ± 1.43	0.63 ± .81	2.27 ± 1.05	**<0.001**[b]
Duration of anesthesia (min), (mean ± SD)	63.33 ± 18.16	63.67 ± 21.73	58.60 ± 8.95	0.943[a]
Duration of surgery (min), (mean ± SD)	52.0 ± 14.54	51.50 ± 21.78	48.33 ± 8.13	0.710[a]
Time required for recovery (min), (mean ± SD)	28.20 ± 6.36	27.13 ± 6.08	27.0 ± 3.85	0.822[a]
MAS (5^{th} min), (mean ± SD)	7.20 ± .81	7.23 ± 1.01	7.73 ± .64	**0.041**[a]
MAS (10-5^{th} min), (mean ± SD)	1.10 ± .31	1.43 ± .73	0.97 ± .32	**0.002**[a]
MAS (15-5^{th} min), (mean ± SD)	2.43 ± .73	2.40 ± .86	1.93 ± .37	**0.005**[a]

Data are presented as mean ± standard deviation or n(%). ASA = American Society of Anesthesiologists score, MAS = The Modified Aldrete Score, COHb = Carboxyhemoglobin level in the pulse CO-oximeter, 10-5^{th} = difference score of MAS measurement between 10^{th} and 5^{th} minutes; 15-5^{th} = difference score of MAS measurement between 15^{th} and 5^{th} minutes. a Mann-Whitney U test, b Independent samples t-test.

79 Methemoglobin and Nitric Oxide Therapy in Ugandan Children Hospitalized for Febrile Illness: Results From a Prospective Cohort Study and Randomized Double-blind Placebo-controlled Trial

Conroy AL, Hawkes M, Hayford K, Hermann L, McDonald CR, Sharma S, Namasopo S, Opoka RO, John CC, Liles WC, Miller C, Kain KC. *BMC Pediatr*. 2016 Nov 4;16(1):177.

Background

Exposure of red blood cells to oxidants increases production of methemoglobin (MHb) resulting in impaired oxygen delivery to tissues. There are no reliable estimates of methemoglobinemia in low resource clinical settings. Our [investigators'] objectives were to: i) evaluate risk factors for methemoglobinemia in Ugandan children hospitalized with fever (study 1); and ii) investigate MHb responses in critically ill Ugandan children with severe malaria treated with inhaled nitric oxide (iNO), an oxidant that induces MHb in a dose-dependent manner (study 2).

Methods

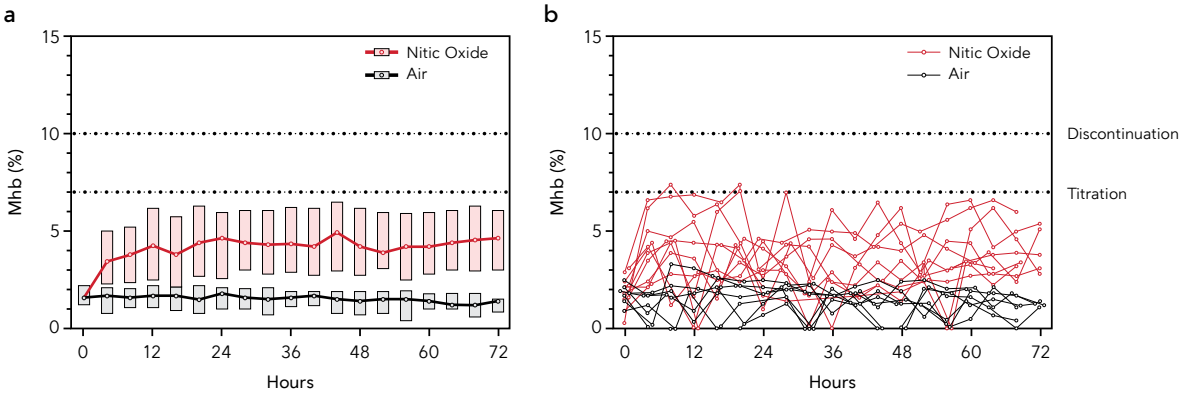
Two prospective studies were conducted at Jinja Regional Referral Hospital in Uganda between 2011 and 2013. Study 1, a prospective cohort study of children admitted to hospital with fever (fever cohort, n = 2089 children 2 months to 5 years). Study 2, a randomized double-blind placebo-controlled parallel arm trial of room air placebo vs. 80 ppm iNO as an adjunctive therapy for children with severe malaria (RCT, n = 180 children 1-10 years receiving intravenous artesunate and 72 h of study gas). The primary outcomes were: i) masimo pulse co-oximetry elevated MHb levels at admission (>2 %, fever cohort); ii) four hourly MHb levels in the RCT.

Results

In the fever cohort, 34 % of children admitted with fever had elevated MHb at admission. Children with a history of vomiting, delayed capillary refill, elevated lactate, severe anemia, malaria, or hemoglobinopathies had increased odds of methemoglobinemia ($p < 0.05$ in a multivariate model). MHb levels at admission were higher in children who died (n = 89) compared to those who survived (n = 1964), p = 0.008. Among children enrolled in the iNO RCT, MHb levels typically plateaued within 12-24 h of starting study gas. MHb levels were higher in children receiving iNO compared to placebo, and MHb > 10 % occurred in 5.7 % of children receiving iNO. There were no differences in rates of study gas discontinuation between trial arms.

Conclusion

Hospitalized children with evidence of impaired oxygen delivery, metabolic acidosis, anemia, or malaria were at risk of methemoglobinemia. However, we [study investigators] demonstrated high-dose iNO could be safely administered to critically ill children with severe malaria with appropriate MHb monitoring.



MHb levels in children with severe malaria randomized to room air or nitric oxide as an adjunctive therapy to intravenous artesunate. **a** Box and whisker plots showing the median (IQR) and 95 % CI for the trial arms at scheduled four hourly MHb checks. **b** Representative MHb plots for a random subset (10%) of study participants (n = 7 placebo arm, n = 10 nitric oxide arm)

80 Methaemoglobinemia after Liposuction under Tumescent Local Anaesthesia — Diagnostic Value of Pulse Oximetry

Brandt S, Kimberger O, Weber B, Klose A, Stockmann S, Schmeller W, Gehring H, Kellner P. *World J Plast Surg*. 2022 Mar;11(1):111-116.

Background

Tumescent local anaesthesia with prilocain can lead to clinically significant methemoglobin levels. New generation multiple wavelength pulse oximeters (e. g. Masimo Radical 7®) can measure methemoglobin levels.

Methods

In this prospective observational study we [study investigators] compared the venous methemoglobin levels and the corresponding pulse oximetric values of the Radical 7® in patients undergoing tumescent local anaesthesia for liposuction procedures. The measurements were performed in Hanseklinik, Luebeck, Germany between 2008 and 2011.

Results

In 133 patients, we [study investigators] measured a maximum methemoglobin level of 18 per cent. In a Bland-Altman analysis we [study investigators] found a mean bias of +2.2 % (-4.1 to 8.4 limits of agreement) for pulse oximetric values compared to hemoximetry.

Conclusion

Pulse oximetric measurement of methemoglobin is an early-warning tool for the detection of clinically significant methaemoglobinemia in patients with tumescent local anaesthesia.

Venous Blood Gas Parameters

Time point	pH	BE (mmol-l^{-1})	Lactate (mmol-l^{-1})	MetHb (%)	tHb (g-dl^{-1})
Preoperative n = 133	7.35 ± 0.05	-1.2 ± 1.8	1.8 ± 0.6	0.4 ± 0.3	14.1 ± 1.0
Postoperative n = 41	7.31 ± 0.05	-8.5 ± 9.4	3.0 ± 1.0	8.5 ± 2.7	12.7 ± 1.0
Evening n = 50	7.35 ± 0.04	-5.9 ± 2.5	2.5 ± 0.8	8.2 ± 3.4	12.1 ± 0.9
Next morning n = 57	7.39 ± 0.03	-3.2 ± 1.8	1.6 ± 0.8	5.5 ± 3.0	11.7 ± 0.9

Sensitivity and specificity of %SpMet® for the detection of methaemoglobinemia ≥ 8 %.

Variable	Parameter	95% confidence interval
Sensitivity	1.00	0.93 to 1.00
Specificity	0.72	0.65 to 0.77
Positive Predictive Value	0.45	0.36 to 0.54
Negative Predictive Value	1.00	0.98 to 1.00

03: rainbow Acoustic Monitoring

81 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.

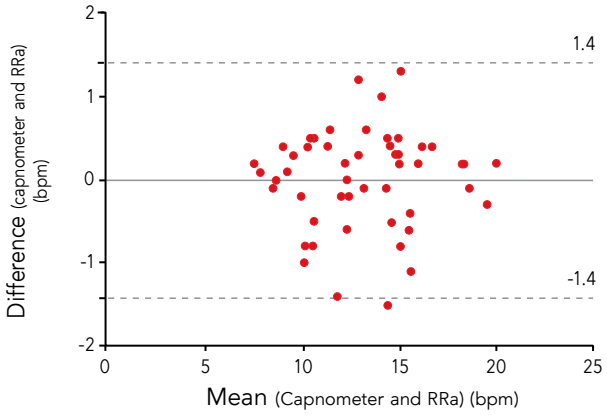
Methods

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.



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

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.

Masimo-supported Study

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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

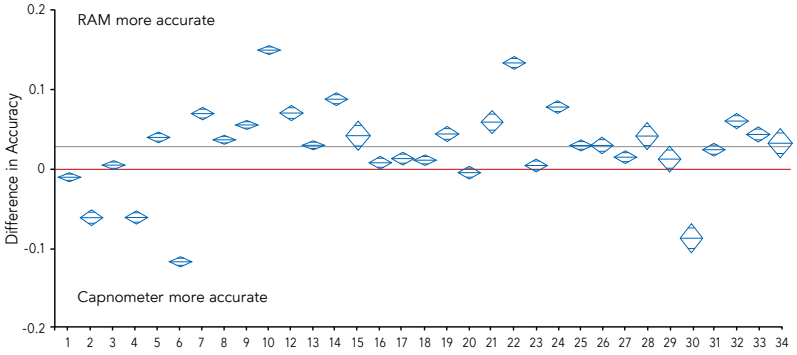
Current methods for monitoring ventilatory rate have limitations including poor accuracy and precision and low patient tolerance. In this study, we [study investigators] evaluated a new acoustic ventilatory rate monitoring technology for accuracy, precision, reliability, and the ability to detect pauses 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.



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

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

83

Accuracy of Acoustic Respiration Rate Monitoring in Pediatric Patients

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 [study investigators] 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

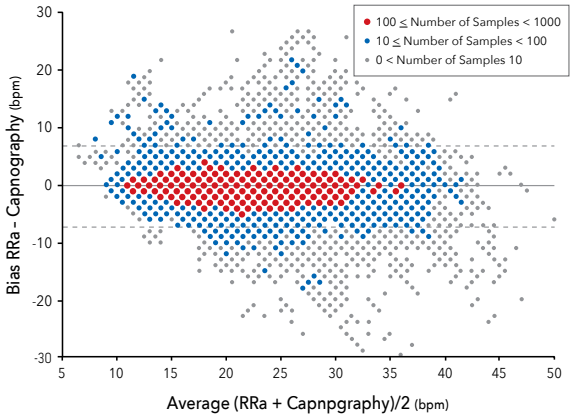
Continuous respiration rate data were recorded from RRa and capnography. In a subset of patients, intermittent respiration rate from thoracic impedance pneumography was also recorded. The reference method, counted respiratory rate by the retrospective analysis of the RRa, and capnographic waveforms while 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.

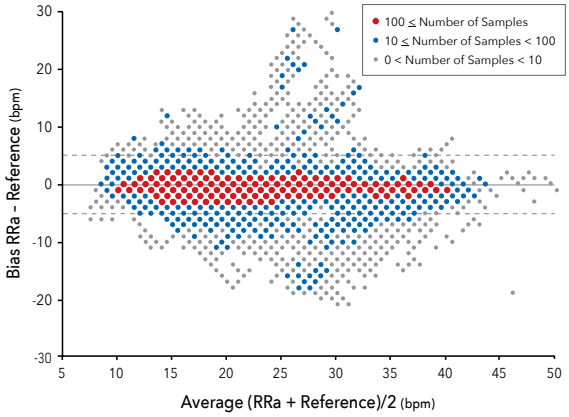
Results

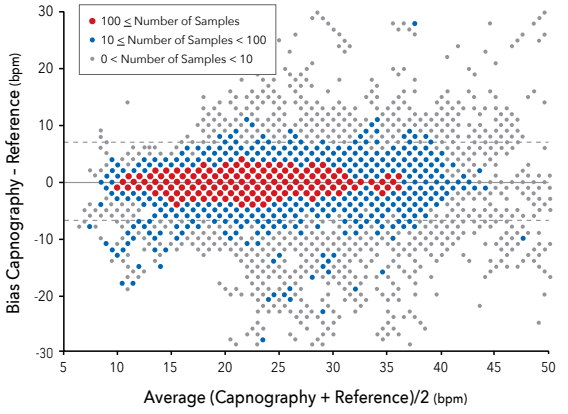
Thirty-nine of 40 patients (97.5%) demonstrated good tolerance of the acoustic sensor, whereas 25 of 40 patients (62.5%) demonstrated good tolerance of the nasal cannula. Intermittent thoracic impedance produced erroneous respiratory rates (>50 b.min-1 from the other methods) on 47% of occasions. The 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.







Masimo-supported Study

84

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 [investigators'] 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

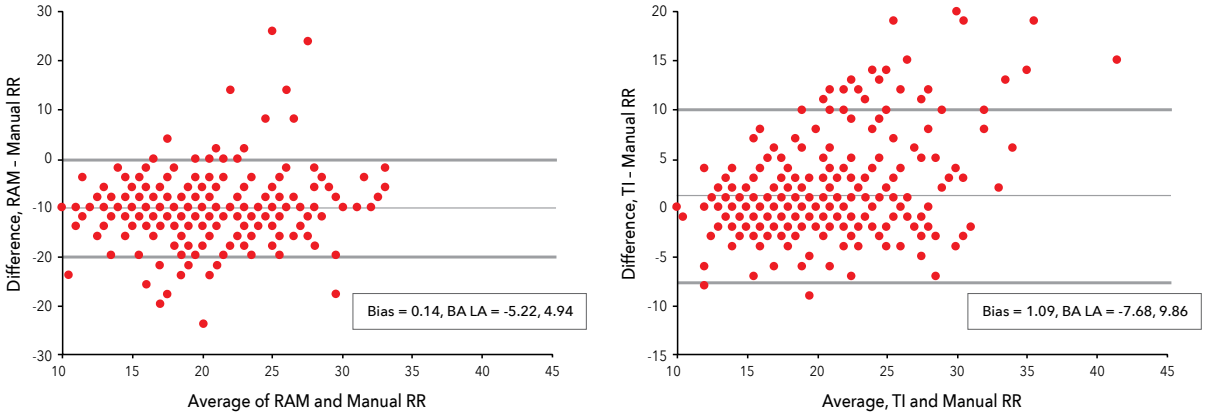
Sixty-two children (2-16 years old) were admitted after tonsillectomy or receiving postoperative patient/parental-controlled analgesia. RR was measured at regular intervals by RAM, TI, and manual count. Each TI or RAM alarm resulted in a clinical evaluation to categorize as a true or false alarm. To 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.



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

85 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.

Comparison of three monitors for: a) Detection of apnea compared to the reference method of direct clinical observation of patients and; b) Accuracy of respiration rate measurement compared to the manual counting of breaths, in patients during upper GI endoscopy.

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]
Positive Predictive Value=(TP/[TP+FP]) [CI], %	na	50 [24–75]	7.4 [3.3–14]	38 [13–68]
Negative Predictive Value=(TN/[TN+FN]) [CI], %	na	97 [92.1–99.4]	81 [54.3–95.6]	95 [87–98]
B	**Clinical Observation**	**RRa Monitoring**	**Capnometry**	**Impedance Pneumography**
Respiration rate bias +/- Precision [CI] (bpm)	na	0 +/- 1.0* [-0.7–0.7]	4.8 +/- 15.1 [2.0–7.6]	0.4 +/- 5.9* [-0.7–1.5]
Respiration rate 95% limits of agreement (bpm)	na	-1.9–1.9	-24.8–34.5	-11.1–11.9

Na=Not Applicable; TP=True Positive; FN=False Negative; TN=True Negative; FP=False Positve; CI=95% Confidence Interval.
*Difference was significant compared to capnometry, p≤0.05.

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.

86

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).

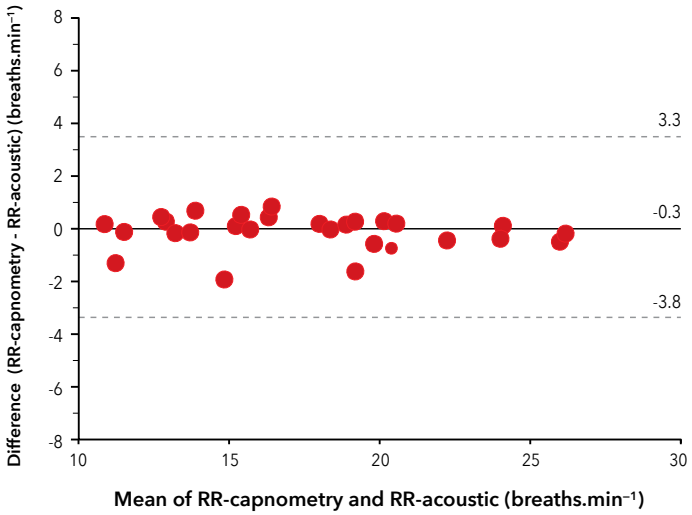
Of the 99,771 data triplets collected, only 85,520 (86%) were included; 12,021 (84%) were not studied due to failure of capnometry and 2240 (16%) due to failure of the acoustic method.

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.



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

87 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 [study investigators] 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)	ARMS (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.

88

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

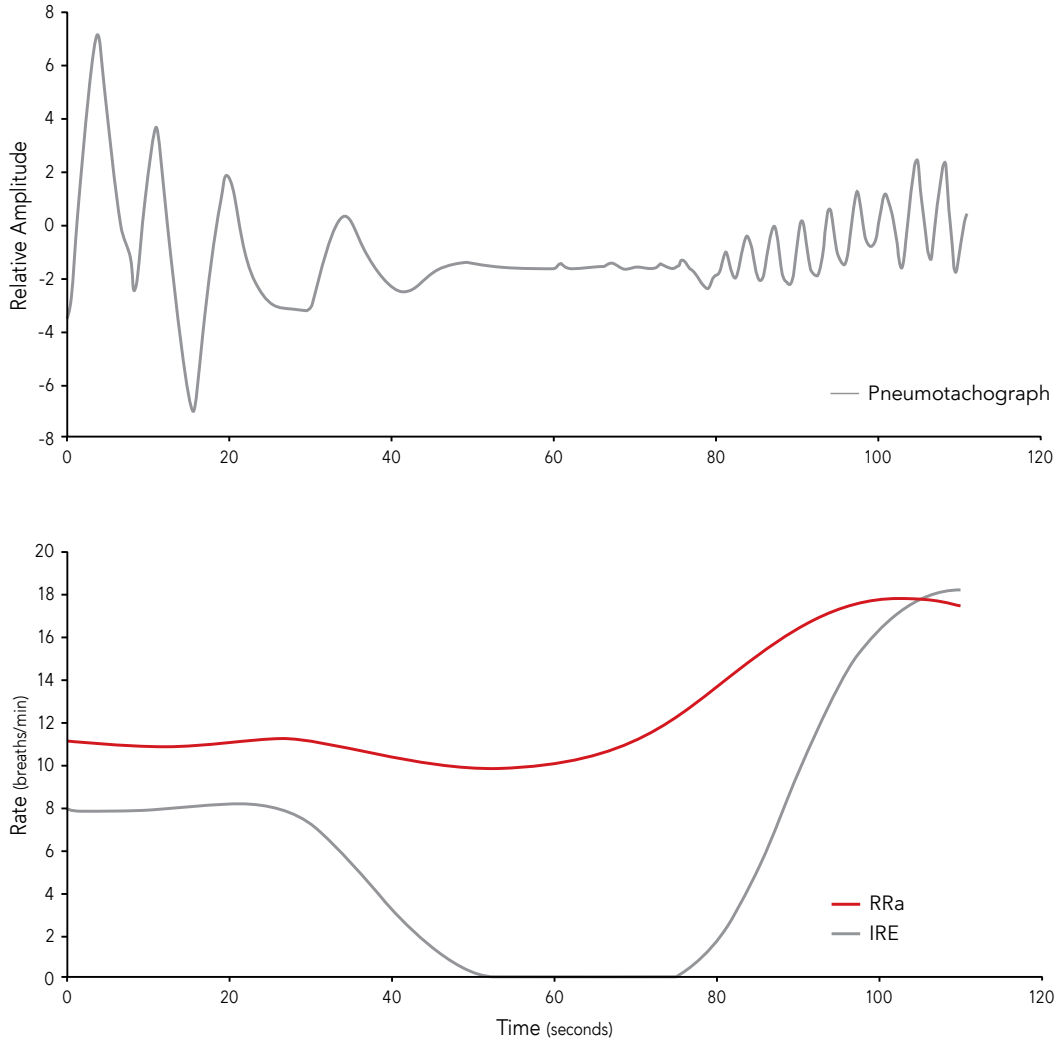
Accurate monitoring of respiratory rate may be useful for the early detection of patient deterioration. Monitoring of respiratory rate in the operating room under general anesthesia by spirometry is technically straightforward and demonstrates high fidelity. Accurate measurement of the respiratory rate 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 technology for respiratory rate monitoring, which has been demonstrated to 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 [study investigators] 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).



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: Hemodynamic Monitoring

89 Reduced Mortality with Noninvasive Hemodynamic Monitoring of Shock

Hata JS, Stotts C, Shelsky C, Bayman EO, Frazier A, Wang J, Nickel EJ. *J Crit Care*. 2011 Apr;26(2):224.e1-8.

Purpose

This study compared clinical outcomes associated with exposure to pulmonary artery catheters (PACs), central venous catheters (CVCs), arterial pressure waveform analysis for cardiac output (APCO), or no central monitoring (NCM) in patients with shock.

Materials and Methods

We [study investigators] assessed 6929 consecutive patients from 2003 to 2006 within a surgical intensive care unit of a university hospital, identifying 237 mechanically ventilated patients with shock.

Results

Adjusted for severity of illness, use of APCO monitoring, compared with other options, was associated with reduced intensive care unit mortality (odds ratio [OR], 0.37; 95% confidence interval [CI], 0.18-0.77) and 28-day mortality (OR, 0.43; 95% CI, 0.22-0.85). Other monitors were not associated with changes of 28-day mortality (CVC: OR, 0.63; 95% CI, 0.34-1.17; PAC: OR, 0.78; 95% CI, 0.36-1.69) or were associated with increased risk (NCM: OR, 2.29; 95% CI, 1.14-4.61). There were significant differences in the fluid and vasoactive drug prescriptions among the groups.

Conclusion

This study supports an association between the use of APCO monitoring and reduction in mortality in shock compared with traditional methods of monitoring. Although it is impossible to exclude the role of unrecognized/unrecorded differences among the groups, these findings may result from differences in supportive care, directed by monitor technology.

Mortality and length of stay data associated with monitor exposure in the defined shock cohort

Monitor	No. of patients (n)	ICU mortality proportion	28-d mortality proportion	Median days of mechanical ventilation (95% CI)	Median ICU length of stay (95% CI)	Median hospital length of stay (95% CI)
NCM	43	0.37	0.40	3 (1-15)	3 (1-15)	13 (1-46)
PAC	38	0.32	0.26	15 (2-95)	16 (2-97)	25 (2-201)
CVC	69	0.20	0.28	7 (1-25)	8 (1-29)	22 (1-67)
APCO	87	0.13	0.16	9 (2-45)	11 (2-41)	24 (6-127)
Total	237	0.22	0.25	8 (1-40)	9 (1-40)	22 (1-96)
P		.007[a]	.033[a]	<.001[b]	<.001[b]	.010[b]

[a] Pearson χ^2.
[b] Nonparametric Kruskal-Wallis test.

90 Effect of a Perioperative, Cardiac Output-guided Hemodynamic Therapy Algorithm on Outcomes Following Major Gastrointestinal Surgery: A Randomized Clinical Trial and Systematic Review

Pearse RM, Harrison DA, MacDonald N, Gillies MA, Blunt M, Ackland G, Grocott MP, Ahern A, Griggs K, Scott R, Hinds C, Rowan K; OPTIMISE Study Group. *JAMA*. 2014;311(21): 2181-90.

Importance

Small trials suggest that postoperative outcomes may be improved by the use of cardiac output monitoring to guide administration of intravenous fluid and inotropic drugs as part of a hemodynamic therapy algorithm.

Objective

To evaluate the clinical effectiveness of a perioperative, cardiac output–guided hemodynamic therapy algorithm.

Design, Setting, and Participants

OPTIMISE was a pragmatic, multicenter, randomized, observer-blinded trial of 734 high-risk patients aged 50 years or older undergoing major gastrointestinal surgery at 17 acute care hospitals in the United Kingdom. An updated systematic review and meta-analysis were also conducted including randomized trials published from 1966 to February 2014.

Interventions

Patients were randomly assigned to a cardiac output–guided hemodynamic therapy algorithm for intravenous fluid and inotrope (dopexamine) infusion during and 6 hours following surgery (n=368) or to usual care (n=366).

Main Outcomes and Measures

The primary outcome was a composite of predefined 30-day moderate or major complications and mortality. Secondary outcomes were morbidity on day 7; infection, critical care–free days, and all-cause mortality at 30 days; all-cause mortality at 180 days; and length of hospital stay.

Results

Baseline patient characteristics, clinical care, and volumes of intravenous fluid were similar between groups. Care was nonadherent to the allocated treatment for less than 10% of patients in each group. The primary outcome occurred in 36.6% of intervention and 43.4% of usual care participants (relative risk [RR], 0.84 [95% CI, 0.71-1.01]; absolute risk reduction, 6.8% [95% CI, −0.3% to 13.9%]; P = .07). There was no significant difference between groups for any secondary outcomes. Five intervention patients (1.4%) experienced cardiovascular serious adverse events within 24 hours compared with none in the usual care group. Findings of the meta-analysis of 38 trials, including data from this study, suggest that the intervention is associated with fewer complications (intervention, 488/1548 [31.5%] vs control, 614/1476 [41.6%]; RR, 0.77 [95% CI, 0.71-0.83]) and a nonsignificant reduction in hospital, 28-day, or 30-day mortality (intervention, 159/3215 deaths [4.9%] vs control, 206/3160 deaths [6.5%]; RR, 0.82 [95% CI, 0.67-1.01]) and mortality at longest follow-up (intervention, 267/3215 deaths [8.3%] vs control, 327/3160 deaths [10.3%]; RR, 0.86 [95% CI, 0.74-1.00]).

Conclusions and Relevance

In a randomized trial of high-risk patients undergoing major gastrointestinal surgery, use of a cardiac output–guided hemodynamic therapy algorithm compared with usual care did not reduce a composite outcome of complications and 30-day mortality. However, inclusion of these data in an updated meta-analysis indicates that the intervention was associated with a reduction in complication rates.

Results for the Primary Outcome[a]

Outcomes	Cardiac Output–Guided Hemodynamic Therapy Algorithm, No. (%) (n = 366)	Usual Care, No. (%) (n = 364)
Composite of predefined moderate or major postoperative complications and mortality at 30d following surgery[b]	134 (36.6)	158 (43.4)
Individual elements		
Mortality	12 (3.3)	11 (3.0)
Pulmonary embolism	4 (1.1)	1 (0.3)
Myocardial ischemia or infarction	10 (2.7)	8 (2.2)
Arrhythmia	39 (10.7)	40 (11.0)
Cardiac or respiratory arrest	16 (4.4)	14 (3.8)
Limb or digital ischemia	2 (0.5)	1 (0.3)
Cardiogenic pulmonary edema	1 (0.3)	2 (0.5)
Acute respiratory distress syndrome	3 (0.8)	4 (1.1)
Gastrointestinal bleeding	13 (3.6)	8 (2.2)
Bowel infarction	2 (0.5)	5 (1.4)
Anastomotic breakdown	12 (3.3)	16 (4.4)
Paralytic ileus	20 (5.5)	27 (7.4)
Acute psychosis	3 (0.8)	8 (2.2)
Stroke	1 (0.3)	0
Acute kidney injury	17 (4.6)	17 (4.7)
Infection, source uncertain	11 (3.0)	9 (2.5)
Urinary tract infection	9 (2.5)	9 (2.5)
Surgical site infection[c]	22 (6.0)	39 (10.7)
Organ/space infection	20 (5.5)	36 (9.9)
Bloodstream infection	6 (1.6)	15 (4.1)
Nosocomial pneumonia	36 (9.8)	39 (10.7)
Postoperative hemorrhage	6 (1.6)	4 (1.1)
Self-assessment of blinding for outcome assessment[d]		
Assessor suitably blinded	342 (94.2)	349 (96.7)
Assessor may have known allocation	9 (2.5)	6 (1.7)
Assessor knew allocation[e]	12 (3.3)	6 (1.7)

[a] Reports complications; some patients developed more than 1 complication. Data do not include 1 patient in the usual care group who was randomized in error and 3 patients (1 in the usual care group and 2 in the hemodynamic therapy group) who withdrew consent. The predefined complication of other infections of the urinary tract did not occur in any patient.

[b] Relative risk, 0.84; 95% CI, 0.71-1.01; P=.07.

[c] Superficial and deep surgical site infection are presented as a single data point.

[d] Six patients (3 in the hemodynamic therapy group and 3 in the usual care group) were missing data on self-assessment of blinding of outcome assessment.

[e] Includes 3 patients (2 in the hemodynamic therapy group and 1 in the usual care group) who died within 30 days.

91 Multidisciplinary Perioperative Protocol in Patients Undergoing Acute High-risk Abdominal Surgery

Tengberg LT, Bay-Nielsen M, Bisgaard T, Cihoric M, Lauritsen ML, Foss NB; AHA study group. *Br J Surg*. 2017; 104:463-471.

Background

Acute high-risk abdominal (AHA) surgery carries a very high risk of morbidity and mortality and represents a massive healthcare burden. The aim of the present study was to evaluate the effect of a standardized multidisciplinary perioperative protocol in patients undergoing AHA surgery.

Methods

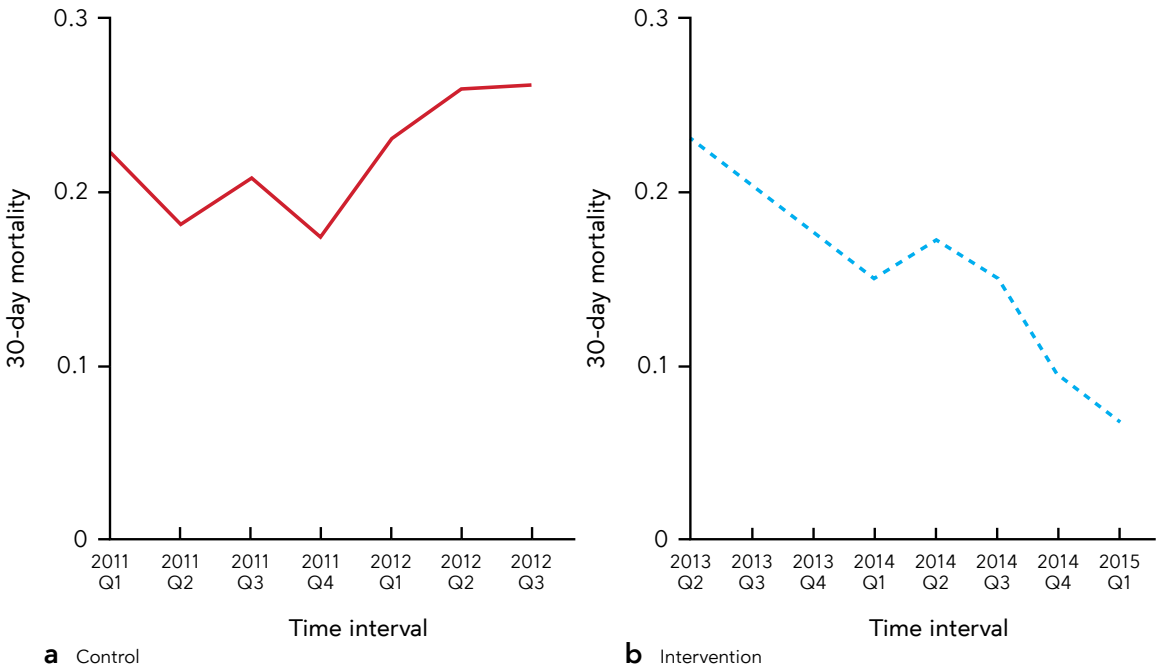
The AHA study was a prospective single-centre controlled study in consecutive patients undergoing AHA surgery, defined as major abdominal pathology requiring emergency laparotomy or laparoscopy including reoperations after elective gastrointestinal surgery. Consecutive patients were included after initiation of the AHA protocol as standard care. The intervention cohort was compared with a predefined, consecutive historical cohort of patients from the same department. The protocol involved continuous staff education, consultant-led attention and care, early resuscitation and high-dose antibiotics, surgery within 6 h, perioperative stroke volume-guided haemodynamic optimization, intermediate level of care for the first 24 h after surgery, standardized analgesic treatment, early postoperative ambulation and early enteral nutrition. The primary outcome was 30-day mortality.

Results

Six hundred patients were included in the study and compared with 600 historical controls. The unadjusted 30-day mortality rate was 21·8 per cent in the control cohort compared with 15·5 per cent in the intervention cohort (P = 0·005). The 180-day mortality rates were 29·5 and 22·2 per cent respectively (P = 0·004).

Conclusion

The introduction of a multidisciplinary perioperative protocol was associated with a significant reduction in postoperative mortality in patients undergoing AHA surgery. NCT01899885 (http://www.clinicaltrials.gov).



Quarterly 30-day mortality in a control and b intervention cohorts. Q1, January–March; Q2, April–June; Q3, July–September; Q4, October–December

05: Brain Monitoring

92 Association of Electroencephalogram Trajectories During Emergence from Anaesthesia with Delirium in the Postanaesthesia Care Unit: An Early Sign of Postoperative Complications

Hesse S, Kreuzer M, Hight D, Gaskell A, Devari P, Singh D, Taylor NB, Whalin MK, Lee S, Sleigh JW, García PS. *Br J Anaesth*. 2019 May;122(5):622-634.

Background

Postoperative delirium is associated with an increased risk of morbidity and mortality, especially in the elderly. Delirium in the postanaesthesia care unit (PACU) could predict adverse clinical outcomes.

Methods

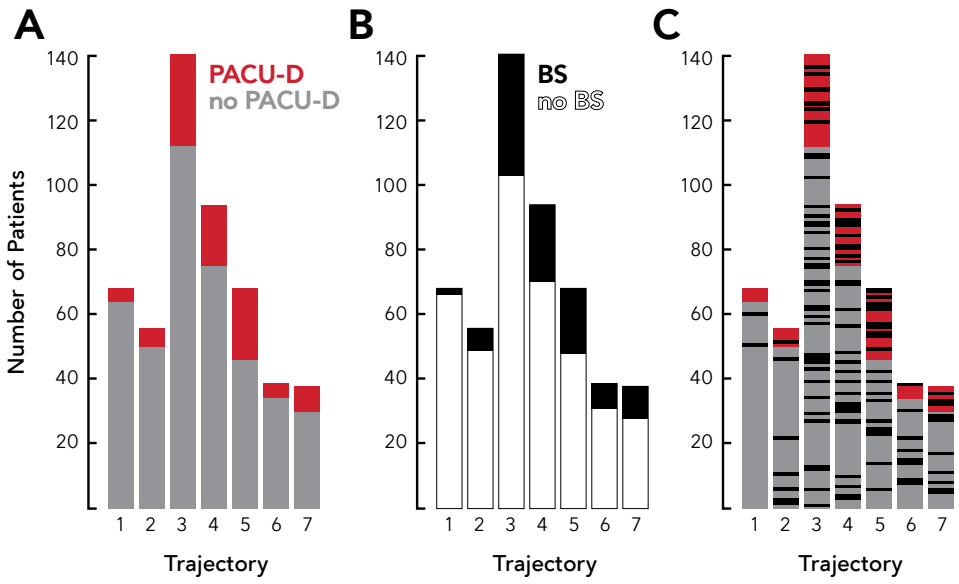
We [study researchers] investigated a potential link between intraoperative EEG patterns and PACU delirium as well as an association of PACU delirium with perioperative outcomes, readmission and length of hospital stay. The risk factors for PACU delirium were also explored. Data were collected from 626 patients receiving general anaesthesia for procedures that would not interfere with frontal EEG recording.

Results

Of the 626 subjects enrolled, 125 tested positive for PACU delirium. Whilst age, renal failure, and pre-existing neurological disease were associated with PACU delirium in the univariable analysis, the multivariable analysis revealed the importance of information derived from the EEG, anaesthetic technique, anaesthesia duration, and history of stroke or neurodegenerative disease. The occurrence of EEG burst suppression during maintenance [odds ratio (OR)=1.86 (1.13-3.05)] and the type of EEG emergence trajectory may be predictive of PACU delirium. Specifically, EEG emergence trajectories lacking significant spindle power were strongly associated with PACU delirium, especially in cases that involved ketamine or nitrous oxide [OR=6.51 (3.00-14.12)]. Additionally, subjects with PACU delirium were at an increased risk for readmission [OR=2.17 (1.13-4.17)] and twice as likely to stay >6 days in the hospital.

Conclusion

Specific EEG patterns were associated with PACU delirium. These findings provide valuable information regarding how the brain reacts to surgery and anaesthesia that may lead to strategies to predict PACU delirium and identify key areas of investigation for its prevention.



Bar plots of the EEG trajectory (1–7) compared with (A) presence and absence of PACU delirium (PACU-D), (B) presence and absence of burst suppression, and (C) PACU-D and burst suppression relationship. (A) Patients with emergence trajectories 1, 2, and 6 have the lowest PACU-D (red) to no PACU-D (gray) ratio, and those with trajectories 3, 4, and 5 have the highest PACU-D to no PACU-D ratio. (B) Black indicates the number of patients with burst suppression during maintenance; white indicates the number of patients without burst suppression. (C) This plot is a combination of data presented in (A) and (B). Gray and red indicate the number of patients without PACU-D (gray) and with PACU-D (red). Individual patients who exhibited burst suppression during maintenance are indicated with black bars. No significant interaction between maintenance burst suppression and emergence trajectory (P=0.591) was observed.

93 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.

Efficacy and Recovery End Points across Patient Groups

	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)

* *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

Masimo-supported Study

94 Impact of Processed Electroencephalography in Cardiac Surgery: A Retrospective Analysis

Jarry S, Halley I, Calderone A, Momeni M, Deschamps A, Richebé P, Beaubien-Souligny W, Denault A, Couture EJ.
J Cardiothorac Vasc Anesth. 2022 Mar 31:S1053-0770(22)00210-5.

Objective

The use of brain function monitoring with processed electroencephalography (pEEG) during cardiac surgery is gaining interest for the optimization of hypnotic agent delivery during the maintenance of anesthesia. The authors sought to determine whether the routine use of pEEG-guided anesthesia is associated with a reduction of hemodynamic instability during cardiopulmonary bypass (CPB) separation and subsequently reduces vasoactive and inotropic requirements in the intensive care unit.

Design

This is a retrospective cohort study based on an existing database.

Setting

A single cardiac surgical center.

Participants

Three hundred patients undergoing cardiac surgery, under CPB, between December 2013 and March 2020.

Interventions

None.

Measurements and Main Results

One hundred and fifty patients had pEEG-guided anesthesia, and 150 patients did not have a pEEG-guided anesthesia. Multiple logistic regression demonstrated that pEEG-guided anesthesia was not associated with a successful CPB separation ($p = 0.12$). However, the use of pEEG-guided anesthesia reduced by 57% the odds of being in a higher category for vasoactive inotropic score compared to patients without pEEG (odds ratio = 0.43; 95% confidence interval: 0.26-0.73; $p = 0.002$). Duration of mechanical ventilation, fluid balance, and blood losses were also reduced in the pEEG anesthesia-guided group ($p < 0.003$), but there were no differences in organ dysfunction duration and mortality.

Conclusion

During cardiac surgery, pEEG-guided anesthesia allowed a reduction in the use of inotropic or vasoactive agents at arrival in the intensive care unit. However, it did not facilitate weaning from CPB compared to a group where pEEG was unavailable. A pEEG-guided anesthetic management could promote early vasopressor weaning after cardiac surgery.

Peri-Operative Outcomes

	Anesthesia without pEEGG guidance (n=150)	Anesthesia with pEEGG guidance (n=150)	*P* value
CPB Separation			
Successful weaning	90 (60)	108 (72)	0.028
Unsuccessful weaning	60 (40)	42 (28)	
Difficult	52 (35)	38 (25)	0.078
Complex	8 (5)	4 (3)	0.239
Intraoperative bleeding (mL)	500 [300-700]	400 [282.5-500]	0.002
Post-operative outcomes			
Vasoactive Inotropic Score (VIS) at ICU admission[a]	8 [2-15]	5 [0-10]	0.003
Duration of mechanical ventilation (hrs)	4 [3-7]	3 [2-4]	<0.001
Delirium	17 (11)	23 (15)	0.297
TPOD[b]	12 [4-35]	16 [4-42]	0.453
Vasopressor time (hrs)	13 [2-39]	19 [4-46]	0.113
Length of stay in the ICU (days)	2 [1-4]	2 [1-4]	0.877
Length of hospital stay (days)	6 [5-8]	6 [5-8]	0.517
Death	1 (0.7)	2 (1.3)	0.562

Values are presented as number (percentage). Variables normaly distributed are presented as mean (standard deviation (SD)). Variables not normally distributed are presented as median (interquartile range (IQR)). [a] Vasoactive Inotropic Score is defined as VIS = dopamine dose (µg/kg/min) + dobutamine dose (µg/kg/min) + 100 x epinephrine dose (µg/kg/min) + 50 x levosimendan dose (µg/kg/min) + 10 x milrinone dose (µg/kg/min) + 10,000 x vasopressin (µg/kg/min) + 100 x norepinephrine dose (µg/kg/min). [b] Time with Persistent Organ Dysfunction (POD) or death during the first 28 days (TPOD) is defined by Stoppe et al. as one or more of the following: mechanical ventilation; vasopressor therapy (ongoing need for vasopressor agents such as norepinephrine, epinephrine, vasopressin, dopamine >5 µg/kg/min, or phenylephrine >50 µg/min); mechanical circulatory support (ongoing need for mechanical devices such as extracorporeal membrane oxygenation (ECMO) or intra-aortic balloon pump; new continuous renal replacement therapy or new intermittent hemodialysis (first to last dialysis session). Therefore, TPOD represents the time for which the patient requires invasive life support after cardiac surgery. TPOD is a continuous variable representative of the burden of care and morbidity during the first 28 days following cardiac surgery and was chosen to circumvent issues arising for using other clinical endpoint such as intensive care unit (ICU) length of stay. Abbreviations: CPB, cardiopulmonary bypass; pEEG, processed electroencephalography

95 SedLine Monitored Sedation and Recovery for Postoperative Ventilated Recipients of Living Donor Liver Transplantation: A Randomized Controlled Trial

Sayed E, Refaat E, Yassen K. *J Anesth Clin Res*. 2015;6(530):2.

Background

Monitoring of adequacy of sedation and careful drug selection can minimize the risks of over sedation and side effects. We [study investigators] evaluate the safety and efficiency of patient state index (PSI) versus Ramsay sedation scale (RSS) on postoperative sedation for living donor liver transplantation (LDLT) recipients.

Methods

Sixty postoperative mechanically ventilated LDLT recipients sedated with desflurane were randomly allocated to either R group (Ramsay group n=30), where sedation assessed using clinical assessment with the RSS, or S group (SEDline group n=30) where sedation assessed with PSI to target sedation depth (50-75). Memorization of five words, Trieger's dot (TT), digit symbol substitution tests (DSST) were recorded. Transesophageal Doppler (TED) parameters were recorded. Duration of mechanical ventilation, postoperative side effects and cost, were recorded.

Results

Mean values of time from cessation of desflurane to eye opening (min), hand squeezing (min), verbal command (min) and to extubation were statistically significant, shorter in S group than R group ($p<0.001$). Five words recall, TT and DSST were better in S group. Patients required norepinephrine were lower in S group than R group (10 (33.3%) vs. 23 (76.7%) P=0.001). Duration of ventilation was shorter in S group than R group (6.83 ± 2.00 vs. 8.26 ± 1.68 hour, P=0.004). Systemic vascular resistance (SVR) and mean blood pressure (MBP) were better preserved in S compared to R group at all measuring points (SVR, MBP after 2hrs sedation 915.73 ± 194.31 vs. 669.20 ± 119.82 dyn.sec.cm-5, $P<0.001$ and 78.03 ± 6.242 vs. 65.13 ± 67.58 mmHg, $P<0.001$, respectively). Postoperative drowsiness, nausea and vomiting were lower in S compared to R group (P=0.000).

Conclusion

Sedation guided with PSI preserved better haemodynamics, enhanced recovery and rapid ventilation weaning at a lower cost compared to RSS monitoring. PSI-augmented sedation monitoring markedly reduced the total dose of sedative used to achieve the same level of clinical sedation without any measurable adverse effects.

Time from cessation of desflurane to different parameters in the two study groups

Data	Group S (n=30)	Group R (n=30)	*P* value
To eye opening (min)	4.07 ± 1.13	15.16 ± 4.47	0.000*
To hand squeezing (min)	4.98 ± 1.64	17.56 ± 4.90	0.000*
Till verbal command (min)	5.45 ± 1.66	24.60 ± 7.33	0.000*
To extubation (min)	10.93 ± 3.03	38.03 ± 18.21	0.000*

Data were presented as mean ± SD, tested by student t-test, P-value<0.05 statistically significant. S.D.: Standard Deviation: *: Significant; S group: SedLine group; R group: Ramsay group

96 High Incidence of Burst Suppression during Propofol Sedation for Outpatient Colonoscopy: Lessons Learned from Neuromonitoring

Bloom J, Wyler D, Torjman MC, Trinh T, Li L, Mehta A, Fitchett E, Kastenberg D, Mahla M, Romo V. *Anesthesiol Res Pract.* 2020 Jun 19;2020:7246570.

Background

Although anesthesia providers may plan for moderate sedation, the depth of sedation is rarely quantified. Using processed electroencephalography (EEG) to assess the depth of sedation, this study investigates the incidence of general anesthesia with variable burst suppression in patients receiving propofol for outpatient colonoscopy. The lessons learned from neuromonitoring can then be used to guide institutional best sedation practice.

Methods

This was a prospective observational study of 119 outpatients undergoing colonoscopy at Thomas Jefferson University Hospital (TJUH). Propofol was administered by CRNAs under anesthesiologists' supervision. The Patient State Index (PSi™) generated by the Masimo SedLine® Brain Root Function monitor (Masimo Corp., Irvine, CA) was used to assess the depth of sedation. PSi data correlating to general anesthesia with variable burst suppression were confirmed by neuroelectrophysiologists' interpretation of unprocessed EEG.

Results

PSi values of <50 consistent with general anesthesia were attained in 118/119 (99.1%) patients. Of these patients, 33 (27.7%) attained PSi values <25 consistent with variable burst suppression. The 118 patients that reached PSi <50 spent a significantly greater percentage (53.1% vs. 42%) of their case at PSi levels <50 compared to PSi levels >50 (p=0.001). Mean total propofol dose was significantly correlated to patient PSi during periods of PSi <25 (R=0.406, p=0.021).

Conclusion

Although providers planned for moderate to deep sedation, processed EEG showed patients were under general anesthesia, often with burst suppression. Anesthesiologists and endoscopists may utilize processed EEG to recognize their institutional practice patterns of procedural sedation with propofol and improve upon it.

Descriptive statistics for PSi data.

	N	Range	Mean	Standard deviation	95.0% CI of mean	*p* value
Mean PSi during GA: PSi 25-50	118	26.5-49.4	*38.8	5.5	37.8-39.9	*<0.001
Mean PSi during deep GA: PSi <25	33	12.8-25.0	*21.1	4.0	19.7-22.6	
Percent of case in sedation: PSi >50	118	2.6-100.0	+42.0	25.7	37.3-46.7	+<0.001
Percent of case during GA: PSi 25-50	118	2.0-97.3	+53.1	24.6	48.6-57.6	
Percent of case during deep GA: PSi <25	33	0.4-77.5	+20.6	21.2	13.1-28.1	

*Statistical significance between the two means. +The three means to be significantly different from one another.

97 Processed Multiparameter Electroencephalogram-Guided General Anesthesia Management Can Reduce Postoperative Delirium Following Carotid Endarterectomy: A Randomized Clinical Trial

Xu N, Li LX, Wang TL, Jiao LQ, Hua Y, Yao DX, Wu J, Ma YH, Tian T, Sun XL. *Front Neurol*. 2021 Jul 12;12:666814.

Background

Patients undergoing carotid endarterectomy (CEA) for severe carotid stenosis are vulnerable to postoperative delirium, a complication frequently associated with poor outcome. This study investigated the impact of processed electroencephalogram (EEG)-guided anesthesia management on the incidence of postoperative delirium in patients undergoing CEA.

Methods

This single-center, prospective, randomized clinical trial on 255 patients receiving CEA under general anesthesia compared the outcomes of patient state index (PSI) monitoring [SEDLine Brain Function Monitor (Masimo, Inc, Irvine, CA)] (standard group, n = 128) with PSI combined with density spectral array(DSA) -guided monitoring (intervention group, n = 127) to reduce the risk of intraoperative EEG burst suppression. All patients were monitored by continuous transcranial Doppler ultrasound (TCD) and near-infrared spectroscopy (NIRS) to avoid perioperative cerebral hypoperfusion or hyperperfusion. According to the surgical process, EEG suppression time was calculated separately for three stages: S1 (from anesthesia induction to carotid artery clamping), S2 (from clamping to declamping), and S3 (from declamping to the end of surgery). The primary outcome was incidence of postoperative delirium according to the Confusion Assessment Method algorithm during the first 3 days post-surgery, and secondary outcomes were other neurologic complications and length of hospital stay.

Results

There were no episodes of cerebral hypoperfusion or hyperperfusion according to TCD and NIRS monitoring in either group during surgery. The incidence of postoperative delirium within 3 days post-surgery was significantly lower in the intervention group than the standard group (7.87 vs. 28.91%, P < 0.01). In the intervention group, the total EEG suppression time and the EEG suppression time during S2 and S3 were shorter (Total, 0 "0" vs. 0 "1.17" min, P = 0.04; S2, 0 "0" vs. 0 "0.1" min, P < 0.01; S3, 0 "0" vs. 0 "0" min, P = 0.02). There were no group differences in incidence of neurologic complications and length of postoperative hospital stay.

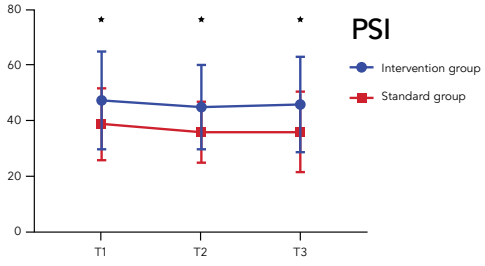
Conclusions

Processed electroencephalogram-guided general anesthesia management, consisting of PSI combined with DSA monitoring, can significantly reduce the risk of postoperative delirium in patients undergoing CEA. Patients, especially those exhibiting hemodynamic fluctuations or receiving surgical procedures that disrupt cerebral perfusion, may benefit from the monitoring of multiple EEG parameters during surgery. Clinical Trial Registration: www.ClinicalTrials.gov, identifier: NCT03622515.

Variable	Intervention group (*n* = 127)	Standard group (*n* = 128)	*P*-value
Postoperative outcome			
Incidence of delirium within 3 days	10 (7.87)	37 (28.91)	0.000
New cerebral infarctions (symptomatic)§§	1 (0.79)	3 (2.34)	0.32
New cerebral infarctions (MRI)§§	33 (25.98)	43 (33.59)	0.18
Intracerebral hemorrhage (MRI)	1 (0.79)	2 (1.56)	0.57
Duration of hospital stay after surgery (days)††	3.99 ± 1.80	4.26 ± 2.00	0.27
Intraoperative EEG Suppression			
Total EEG suppression time (min)*##	0 (0)	0 (1.17)	0.04
Time of EEG suppression in S_1 (min)*##	0 (0)	0 (0.25)	0.13
Time of EEG suppression in S_2 (min)*##	0 (0)	0 (0.1)	0.000
Time of EEG suppression in S_3 (min)*##	0 (0)	0 (0)	0.02

*The values in parenthesis are expressed as percentages unless indicated otherwise. Values are expressed as *median (i.q.r.). S_1 is the stage from induction of anesthesia to clamping the carotid artery. S_2 from clamping to declamping, and S_3 from the declamping to the end of surgery.*

§§ The P value is from the x^2 test, except †† The P value is from the independent-samples t test and the ## The P vale is from the independent-samples Mann-Whitney U test.



PSI at corresponding time points. PSI, patient state index, *P < 0.05 from standard group (statistically significant). The measurement time interval after general anesthesia but before clamping the carotid artery was recorded as baseline reference T1, the time interval after clamping but before declamping was recorded as T2, and the time interval after the declamping and stabilization of cerebral perfusion but before completion of surgery was recorded as T3.

98 Isoelectric Electroencephalography in Infants and Toddlers during Anesthesia for Surgery: An International Observational Study

Yuan I, Xu T, Skowno J, Zhang B, Davidson A, von Ungern-Sternberg BS, Sommerfield D, Zhang J, Song X, Zhang M, Zhao P, Liu H, Jiang Y, Zuo Y, de Graaff JC, Vutskits L, Olbrecht VA, Szmuk P, Kurth CD; BRAIN Collaborative Investigators. *Anesthesiology*. 2022 Aug 1;137(2):187-200.

Background

Intraoperative isoelectric electroencephalography (EEG) has been associated with hypotension and postoperative delirium in adults. This international prospective observational study sought to determine the prevalence of isoelectric EEG in young children during anesthesia. The authors hypothesized that the prevalence of isoelectric events would be common worldwide and associated with certain anesthetic practices and intraoperative hypotension.

Methods

Fifteen hospitals enrolled patients age 36 months or younger for surgery using sevoflurane or propofol anesthetic. Frontal four-channel EEG was recorded for isoelectric events. Demographics, anesthetic, emergence behavior, and Pediatric Quality of Life variables were analyzed for association with isoelectric events.

Results

Isoelectric events occurred in 32% (206 of 648) of patients, varied significantly among sites (9 to 88%), and were most prevalent during pre-incision (117 of 628; 19%) and surgical maintenance (117 of 643; 18%). Isoelectric events were more likely with infants younger than 3 months (odds ratio, 4.4; 95% CI, 2.57 to 7.4; P < 0.001), endotracheal tube use (odds ratio, 1.78; 95% CI, 1.16 to 2.73; P = 0.008), and propofol bolus for airway placement after sevoflurane induction (odds ratio, 2.92; 95% CI, 1.78 to 4.8; P < 0.001), and less likely with use of muscle relaxant for intubation (odds ratio, 0.67; 95% CI, 0.46 to 0.99; P = 0.046]. Expired sevoflurane was higher in patients with isoelectric events during preincision (mean difference, 0.2%; 95% CI, 0.1 to 0.4; P = 0.005) and surgical maintenance (mean difference, 0.2%; 95% CI, 0.1 to 0.3; P = 0.002). Isoelectric events were associated with moderate (8 of 12, 67%) and severe hypotension (11 of 18, 61%) during preincision (odds ratio, 4.6; 95% CI, 1.30 to 16.1; P = 0.018) (odds ratio, 3.54; 95% CI, 1.27 to 9.9; P = 0.015) and surgical maintenance (odds ratio, 3.64; 95% CI, 1.71 to 7.8; P = 0.001) (odds ratio, 7.1; 95% CI, 1.78 to 28.1; P = 0.005), and lower Pediatric Quality of Life scores at baseline in patients 0 to 12 months (median of differences, -3.5; 95% CI, -6.2 to -0.7; P = 0.008) and 25 to 36 months (median of differences, -6.3; 95% CI, -10.4 to -2.1; P = 0.003) and 30-day follow-up in 0 to 12 months (median of differences, -2.8; 95% CI, -4.9 to 0; P = 0.036). Isoelectric events were not associated with emergence behavior or anesthetic (sevoflurane vs. propofol).

Conclusions

Isoelectric events were common worldwide in young children during anesthesia and associated with age, specific anesthetic practices, and intraoperative hypotension.

Characteristics of Isoelectric Events Overall and across Anesthetic Phases

		Overall	Induction	Preincision	Surgical Maintenance	Emergence
Occurrence of isoelectric events	Median [interquartile range]	206 of 648 (31.8%)	54 of 581 (9.3%)	117 of 628 (18.6%)	117 of 643 (18.2%)	42 of 544 (7.7%)
Isoelectric events per patient		13 [4 to 56]	0 [0 to 1]	1 [0 to 14]	1 [0 to 35.8]	0 [0 to 0]
Total isoelectric time (s)		68.9 [13.7 to 276.7]	0 [0 to 4.2]	3.9 [0 to 58.1]	4.3 [0 to 146.4]	0 [0 to 0]
Isoelectric time per event (s)		3.6 [2.8 to 5.6]	0 [0 to 2.6]	2.6 [0 to 4.2]	2.3 [0 to 4]	0 [0 to 0]
Isoelectric time recording time (%)		1.1 [0.3 to 4.4]	0 [0 to 0.9]	0.4 [0 to 5.5]	0.1 [0 to 2.8]	0 [0 to 0]

Occurence is number of patients or percent of patients with isoelectric events (%). Isoelectric events per patient is the number of events per patient who had isoelectric electroencephalography.

99 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.

100 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 [investigators] 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

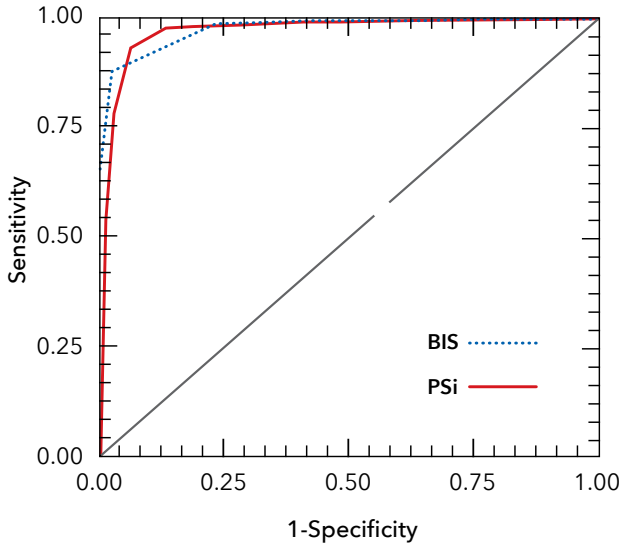
Twenty-two consenting patients scheduled for elective laparoscopic procedures were enrolled in this prospective study. The elapsed time to apply electrodes and obtain a baseline index value was recorded, as were the comparative PSi and BIS values at specific time intervals during the induction, maintenance, 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 [study investigators] 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.



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).

101 Early Neuro-prognostication with the Patient State Index and Suppression Ratio in Post-cardiac Arrest Patients

Kim TY, Hwang SO, Jung WJ, Roh YI, Kim S, Kim H, Cha KC. *J Crit Care*. 2021 Oct;65:149-155.

Purpose

Cardiopulmonary resuscitation guidelines recommend multimodal neuro-prognostication after cardiac arrest using neurological examination, electroencephalography, biomarkers, and brain imaging. The Patient State Index (PSI) and suppression ratio (SR) represent the depth and degree of sedation, respectively. We [study investigators] evaluated the predictive ability of PSI and SR for neuro-prognostication of post-cardiac arrest patients who underwent targeted temperature management.

Methods

This prospective observational study was conducted between January 2017 and August 2020 and enrolled adult patients in an intensive care unit (ICU) with non-traumatic out-of-hospital cardiac arrest with return of spontaneous circulation (ROSC). PSI and SR were monitored continuously during ICU stay, and their maximum, mean, and minimum cutoff values 24 h after ROSC were analyzed to predict poor neurologic outcome and long-term survival.

Results

The final analysis included 103 patients. A mean PSI ≤ 14.53 and mean SR > 36.6 showed high diagnostic accuracy as single prognostic factors. Multimodal prediction using the mean PSI and mean SR showed the highest area-under-the-curve value of 0.965 (95% confidence interval 0.909-0.991). Patients with mean PSI ≤ 14.53 and mean SR > 36.6 had relatively higher long-term mortality rates than those of patients with values >14.53 and ≤ 36.6, respectively.

Conclusions

The PSI and SR are good predictors for early neuro-prognostication in post-cardiac arrest patients.

Maximum, mean, and minimum values of the patient state index or suppression ratio for predicting poor neurologic outcome.

Variables	AUC (95% CI)	Cut-off	Sensitivity (95% CI)	Specificity (95% CI)	PPV (95% CI)	NPV (95% CI)	TP	FP	FN	TN	FPR (95% CI)
Maximum PSI	0.739 (0.643-0.820)	≤25	66.10 (52.6-77.9)	100 (92-100)	100	68.8 (60.6-75.9)	39	0	20	44	0 (0-8)
Minimum PSI	0.915 (0.844-0.961)	<0	0.0	100 (92-100)		42.7 (42.7-42.7)	0	0	44	59	0 (0-8)
Mean PSI	0.924 (0.855-0.967)	≤ 14.53	79.66 (67.2-89.0)	100 (92-100)	100	78.6 (68.9-85.9)	47	0	12	44	0 (0-8)
Maximum SR	0.930 (0.863-0.971)	>94	62.71 (49.1-75.0)	100 (92-100)	100	66.7 (59.0-73.6)	37	0	22	44	0 (0-8)
Minimum SR	0.836 (0.750-0.902)	>6	67.8 (54.4-79.4)	100 (92-100)	100	69.8 (61.5-77.0)	40	0	19	44	0 (0-8)
Mean SR	0.951 (0.889-0.984)	>36.6	81.36 (69.1-90.3)	100 (92-100)	100	80.0 (70.1-87.2)	48	0	11	44	0 (0-8)
PBSS	0.869 (0.788-0.927)	>6	0.0	100 (92-100)		42.7 (42.7-42.7)	0	0	60	43	0 (0-8)
Mean PSI and mean SR	0.965 (0.909-0.991)		81.36 (69.1-90.3)	100 (92.0-100)	100	80.0 (70.1-87.2)	48	0	11	44	0 (0-8)
Mean PSI, mean SR, and PBSS	0.962 (0.905-0.990)		81.36 (69.1-90.3)	100 (92-100)	100	80.0 (70.1-87.2)	48	0	11	44	0 (0-8)

AUC, area under the curve; CI, confidence interval; PSI, Patient State Index; SR, suppression ratio; PBSS, Pittsburg Brain Stem Score, TP, true positive, FP, false positive, FN false negative, TN, true negative; FPR, false positive rate.

102 Perioperative Electroencephalogram Spectral Dynamics Related to Postoperative Delirium in Older Patients

Koch S, Windmann V, Chakravarty S, Kruppa J, Yürek F, Brown EN, Winterer G, Spies C; BioCog Study Group. *Anesth Analg*. 2021 Dec 1;133(6):1598-1607.

Background

Intraoperative electroencephalography (EEG) signatures related to the development of postoperative delirium (POD) in older patients are frequently studied. However, a broad analysis of the EEG dynamics including preoperative, postinduction, intraoperative and postoperative scenarios and its correlation to POD development is still lacking. We [study investigators] explored the relationship between perioperative EEG spectra-derived parameters and POD development, aiming to ascertain the diagnostic utility of these parameters to detect patients developing POD.

Methods

Patients aged ≥65 years undergoing elective surgeries that were expected to last more than 60 minutes were included in this prospective, observational single center study (Biomarker Development for Postoperative Cognitive Impairment [BioCog] study). Frontal EEGs were recorded, starting before induction of anesthesia and lasting until recovery of consciousness. EEG data were analyzed based on raw EEG files and downloaded excel data files. We [study investigators] performed multitaper spectral analyses of relevant EEG epochs and further used multitaper spectral estimate to calculate a corresponding spectral parameter. POD assessments were performed twice daily up to the seventh postoperative day. Our [investigators'] primary aim was to analyze the relation between the perioperative spectral edge frequency (SEF) and the development of POD.

Results

Of the 237 included patients, 41 (17%) patients developed POD. The preoperative EEG in POD patients was associated with lower values in both SEF (POD 13.1 ± 4.6 Hz versus no postoperative delirium [NoPOD] 17.4 ± 6.9 Hz; P = .002) and corresponding γ-band power (POD -24.33 ± 2.8 dB versus NoPOD -17.9 ± 4.81 dB), as well as reduced postinduction absolute γ-band power (POD -7.37 ± 4.52 dB versus NoPOD -5 ± 5.03 dB). The ratio of SEF from the preoperative to postinduction state (SEF ratio) was ~1 in POD patients, whereas NoPOD patients showed a SEF ratio >1, thus indicating a slowing of EEG with loss of unconscious. Preoperative SEF, preoperative γ-band power, and SEF ratio were independently associated with POD (P = .025; odds ratio [OR] = 0.892, 95% confidence interval [CI], 0.808-0.986; P = .029; OR = 0.568, 95% CI, 0.342-0.944; and P = .009; OR = 0.108, 95% CI, 0.021-0.568, respectively).

Conclusions

Lower preoperative SEF, absence of slowing in EEG while transitioning from preoperative state to unconscious state, and lower EEG power in relevant frequency bands in both these states are related to POD development. These findings may suggest an underlying pathophysiology and might be used as EEG-based marker for early identification of patients at risk to develop POD.

Perioperative EEG Parameter	All patients (n = 237)	NoPOD (n=196)	POD (n=41)	*P* value
Preoperative SEF (Hz)[a]	16.8 ± 6.8 (n=119)	17.4 ± 6.9 (n=101)	13.1 ± 4.6 (n=18)	.002
Postinduction SEF (Hz)	12.7 ± 4.3 (n=224)	12.7 ± 3.9 (n=186)	12.4 ± 5.5 (n=38)	.739
Intraoperative SEF (Hz)	12.8 ± 3.6 (n=237)	12.8 ± 3.2 (n=196)	12.4 ± 5.2 (n=41)	.564
Postoperative SEF (Hz)	23.5 ± 10.1 (n=123)	23.5 ± 10.2 (n=106)	23.1 ± 9.6 (n=17)	.868
Preoperative PSI	91.7 ± 4.4 (n=119)	91.9 ± 4.2 (n=101)	90.8 ± 5.4 (n=18)	.407
Postinduction PSI	34.1 ± 8.6 (n=224)	33.9 ± 8.8 (n=186)	35.4 ± 7.9 (n=38)	.306
Intraoperative PSI	33.6 ± 9.4 (n=237)	33.4 ± 9.0 (n=196)	34.3 ± 11.3 (n=41)	.655
Postoperative PSI	85.4 ± 6.5 (n=123)	85.1 ± 6.7 (n=106)	87.1 ± 5.3 (n=17)	.184
SEF ratio[a] (preoperative SEF/intraoperative SEF)	1.26 ± 0.49 (n=112)	1.3 ± 0.49 (95)	0.98 ± 0.36 (n=17)	.003
Ratio PSI (preoperative PSI/intraoperative PSI)	3 ± 1.04 (n=112)	3 ± 0.96 (95)	2.99 ± 1.51 (17)	.973
Burst suppression duration (min)	19 (20/47) (n=224)	17 (16/39) (n=186)	32 (7/200) (n=38)	.227

Preoperative EEG parameter comparing results between NoPOD and POD patients. Data are presented as mean and SD (mean ± SD) or median and 95% CI (median [95% lower limit-upper limit]). Data were calculated by Student t test and Mann-Whitney *U* test for Burst Suppression duration. Abbreviations: CI, confidence interval; EEG, electroencephalography; NoPOD, no postoperative delirium; POD, postoperative delirium; SD, standard deviation; SEF, spectral edge frequency; PSI, patient state index. [a]<.01.

103 Management Based on Multimodal Brain Monitoring May Improve Functional Connectivity and Post-operative Neurocognition in Elderly Patients Undergoing Spinal Surgery

Yang S, Xiao W, Wu H, Liu Y, Feng S, Lu J, Wang T. M. *Front Aging Neurosci*. 2021 Jul 15;13:705287.

Perioperative neurocognitive disorder (PND) is a common condition in elderly patients undergoing surgery. Sedation, analgesia, regional cerebral oxygen saturation (rSO_2), and body temperature are known to be associated with PND, but few studies have examined the contribution of these factors combined in detail. This prospective, randomized, controlled, double-blinded study investigated whether anesthesia management based on multimodal brain monitoring-an anesthesia management algorithm designed by our [investigators'] group-could improve the post-operative cognitive function and brain functional connectivity (FC) in elderly patients undergoing elective spinal surgery with general anesthesia. The patients (aged ≥65 years) were randomized into two groups [control (Group C), n = 12 and intervention (Group I), n = 14]. Patients in Group I were managed with multimodal brain monitoring (patient state index, spectral edge frequency, analgesia nociception index, rSO_2, and temperature), and those in Group C were managed with routine anesthesia management. All patients were pre- and post-operatively evaluated (7 days after surgery) with the Montreal Cognitive Assessment (MoCA). Amplitude of low-frequency fluctuation (ALFF) and FC were analyzed after resting-state functional MRI. Serum C-reactive protein (CRP) and lipopolysaccharide levels were measured, and the correlation between FC and changes in inflammatory marker levels was analyzed. Mean post-operative MoCA score was higher in Group I (24.80 ± 2.09) than in Group C (22.56 ± 2.24) ($p = 0.04$), with no difference in PND incidence between groups (28.57 vs. 16.67%; $p = 0.47$). Group I also showed significantly increased ALFF values in several brain regions after surgery ($p < 0.05$), and FC between the left hippocampus and left orbital inferior frontal gyrus (FG), left middle FG, left superior temporal gyrus, and left precentral gyrus was enhanced ($p < 0.05$), which was negatively correlated with the change in serum CRP (pre vs. post-intervention) ($R = -0.58$, $p = 0.01$). These results suggest that management of elderly patients undergoing surgery by multimodal brain monitoring may improve post-operative neurocognition and FC by reducing systemic inflammation. Clinical Trial Registration: http://www.chictr.org.cn/index.aspx, identifier: ChiCTR1900028024.

Neuropsychological assessment and incidence of PND.

	Group C (*n* = 14)	Group I (*n* = 12)	Effective size	*p*-value
MoCA score (T_0)	21.78 ± 2.73	23.50 ± 2.51	0.66	0.17
MoCA score (T_2)	22.56 ± 2.24	24.80 ± 2.09	1.03	0.04
PND [*n* (%)]	4 (28.57)	2 (16.67)	0.33	0.47

Data are mean ± SD or frequencies.
PND, post-operative neurocognitive disorder; MoCA, Montreal Cognitive Assessment; T0, 1 day before surgery; T2, 7 days after surgery.
$p < 0.05$ was considered as statistically significant.

104 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.

105 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 [study investigators] evaluated absolute and trend accuracy of a new regional oximetry technology in healthy volunteers.

Methods

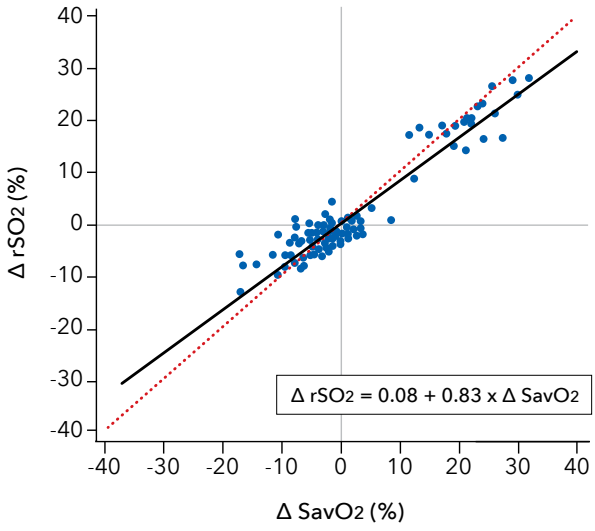
A near-infrared spectroscopy sensor connected to a regional oximetry system (O3, Masimo, Irvine, CA) was placed on the subject's forehead, to provide continuous measurement of regional oxygen saturation (rSO_2). Reference blood samples were taken from the radial artery and internal jugular bulb vein, 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.



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

106 Patient Management Algorithm Combining Processed Electroencephalographic Monitoring with Cerebral and Somatic Near-infrared Spectroscopy: A Case Series

Couture EJ, Deschamps A, Denault AY. *Can J Anaesth*. 2019 May;66(5):532-539.

Purpose

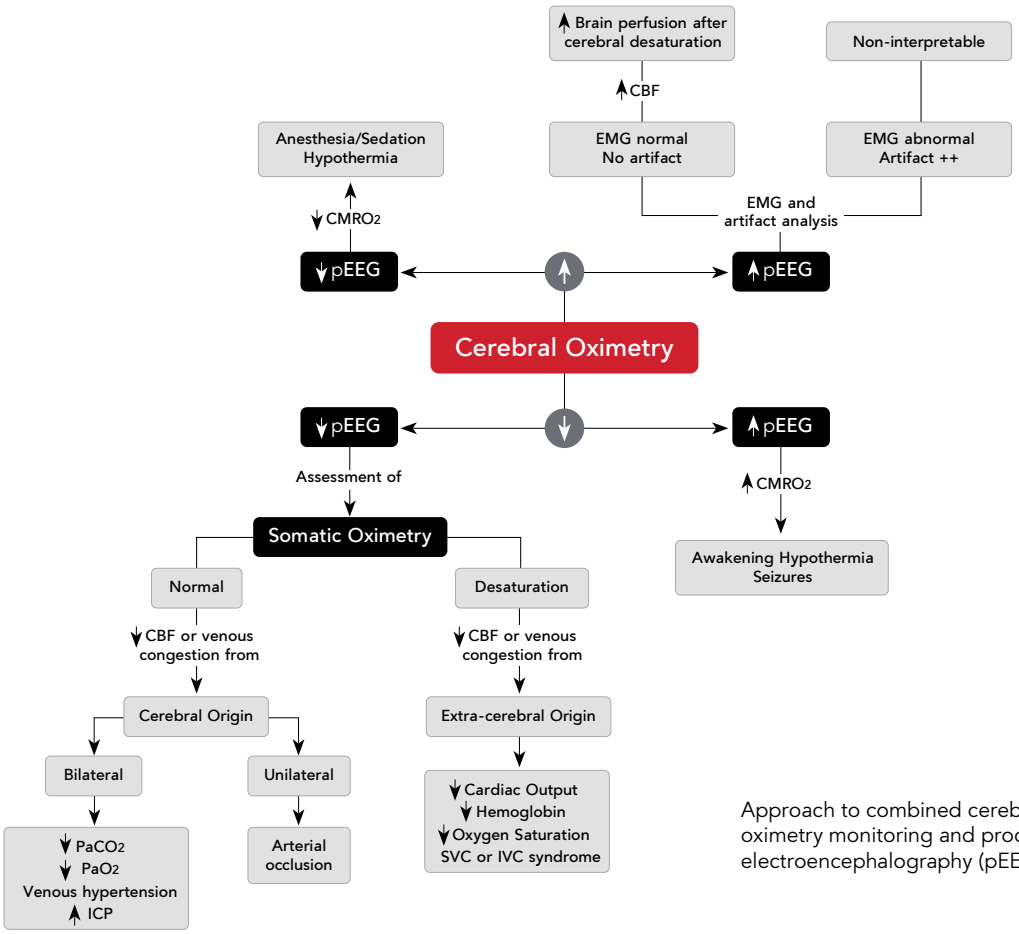
Cerebral oximetry is a monitoring tool used in the perioperative care of cardiac surgery patients to ensure adequate cerebral perfusion and oxygenation. When combined with somatic oximetry, the differential diagnosis of cerebral desaturation can be better identified and managed more specifically, as somatic oximetry serves as a global or localized perfusion monitor (depending on its regional position). The use of processed electroencephalography (pEEG) in cardiac surgery could further guide the management of desaturation episodes, as reductions in pEEG activity without a change in the anesthetic agent level indicate potential cerebral ischemia. Continuous integration of multiple monitoring modalities are thus desirable to assess organ perfusion and organ function.

Clinical Features

Four clinical cases are presented in which the combination of pEEG and cerebro-somatic oximetry assisted with understanding the mechanism of cerebral desaturation encountered during cardiac surgery.

Conclusion

Integrating combinations of different monitoring modalities such as cerebral and somatic oximetry with pEEG can help the diagnosis and treatment of organ malperfusion and related dysfunction.



Approach to combined cerebral oximetry monitoring and processed electroencephalography (pEEG)

107 Brain Co-oximetry: An Useful Non-Invassive Parameter Adjuvant to Standard Perfusion Parameters in Septic Shock

Das D, Mitra K, Das S. *Anesthesia & Clinical Research*. 2021 Feb 4;12(1):1-5.

Background and Aim

Standard monitoring for tissue perfusion includes mixed venous saturation ($CvSO_2$), blood lactate. Cerebral oximetry ($CrSO_2$) non-invasively observes trends in cerebral saturation and it can be used as adjuvant to standard monitoring. The aim of the study is to evaluate septic shock mortality and patient outcome.

Methods

In this study 40 patients were entailed with septic shock at ICU for study period of 10 months. $CrSO_2$ was monitored using "MASIMO O3 Regional Oximetry". Patients were monitored with $CrSO_2$, $CvSO_2$, blood lactate, mean arterial pressure (MAP), arterial oxygen saturation (SaO_2) 6 hourly for 72 hours. Patients with history of cerebrovascular diseases and neurological deficits were excluded from study. IBM SPSS Statistics, Version 24.0. software was used and independent t test, paired t test, Pearson coefficient (r) etc. parameter values were analyzed.pling.

Results

There is significant negative correlation after six hours from admission was noticed between $CrSO_2$ and lactic acid (r=-0.749 to -0.956). Significant positive correlation was noticed between $CrSO_2$ and $CvSO_2$ (r=0.904 to 0.993). In addition, significant positive correlation was also found between $CrSO_2$ and mean arterial pressure (r=0.957 to 0.993) and SaO_2 (r=0.864 to 0.988). Significant difference was also detected between the value of $CrSO_2$ in the survivors (29 patients) and the non-survivors (11 patients) after 72 hours from admission.

Conclusion

$CrSO_2$ could be parameters in patients with shock and it could have a prognostic value in mortality prediction and clinical outcome.

Correlative value of cerebral oximetry with different other parameters.

	Lactate		$CvSo_2$		Sao_2		MAP	
0 hr	-0.956	<0.001	0.993	<0.001	0.988	<0.001	0.976	<0.001
6 hr	-0.946	<0.001	0.976	<0.001	0.973	<0.001	0.966	<0.001
12 hr	-0.938	<0.001	0.982	<0.001	0.981	<0.001	0.99	<0.001
18 hr	-0.899	<0.001	0.981	<0.001	0.972	<0.001	0.988	<0.001
24 hr	-0.876	<0.001	0.904	<0.001	0.981	<0.001	0.982	<0.001
30 hr	-0.937	<0.001	0.972	<0.001	0.98	<0.001	0.965	<0.001
36 hr	-0.767	<0.001	0.967	<0.001	0.888	<0.001	0.97	<0.001
42 hr	-0.865	<0.001	0.986	<0.001	0.95	<0.001	0.987	<0.001
48 hr	-0.831	<0.001	0.982	<0.001	0.982	<0.001	0.993	<0.001
54 hr	-0.862	<0.001	0.989	<0.001	0.962	<0.001	0.967	<0.001
60 hr	-0.79	<0.001	0.979	<0.001	0.864	<0.001	0.988	<0.001
66 hr	-0.808	<0.001	0.988	<0.001	0.927	<0.001	0.957	<0.001
72 hr	-0.749	<0.001	0.977	<0.001	0.869	<0.001	0.986	<0.001
$CrSO_2$	r value	p value	r value	p value	r value	p value	r value	p value

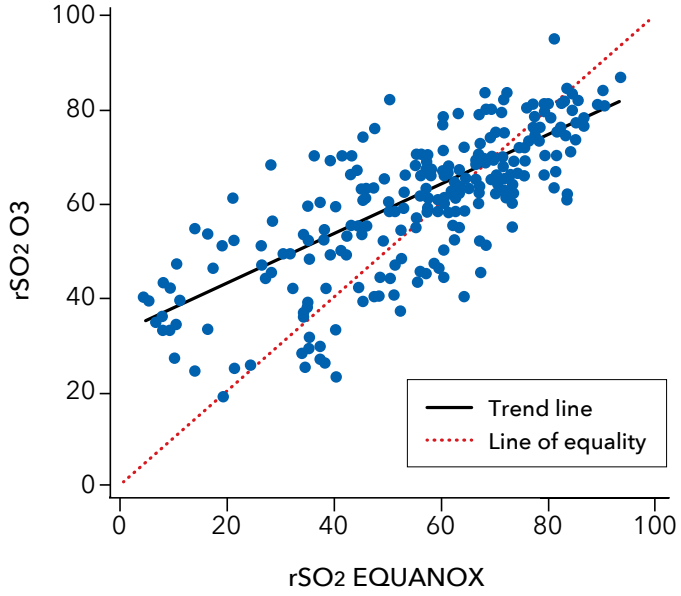
$CrSo_2$-Cerebral oximetry; $CvSo_2$-Central mixed venous oxygen saturation; SaO_2-Arterial Oxygen saturation; MAP-Mean arterial pressure; r-Pearson correlation coefficient; p-Probability. p value <0.05=statistically significant

108 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 [study investigators] 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 [study investigators] 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.



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

109 The Use of Different Components of Brain Oxygenation for the Assessment of Cerebral Haemodynamics: A Prospective Observational Study on COVID-19 Patients

Robba C, Cardim D, Ball L, Battaglini D, Dabrowski W, Bassetti M, Giacobbe DR, Czosnyka M, Badenes R, Pelosi P, Matta B; GeCovid group. *Front Neurol*. 2021 Dec 20;12:735469.

Introduction

The role of near-infrared spectroscopy (NIRS) for the evaluation of cerebral haemodynamics is gaining increasing popularity because of its noninvasive nature. The aim of this study was to evaluate the role of the integral components of regional cerebral oxygenation (rSO_2) measured by NIRS [i.e., arterial-oxyhemoglobin (O_2Hbi) and venous-deoxyhemoglobin (HHbi)-components], as indirect surrogates of cerebral blood flow (CBF) in a cohort of critically ill patients with coronavirus disease 2019 (COVID-19). We [study investigators] compared these findings to the gold standard technique for noninvasive CBF assessment, Transcranial Doppler (TCD).

Methods

Mechanically ventilated patients with COVID-19 admitted to the Intensive Care Unit (ICU) of Policlinico San Martino Hospital, Genova, Italy, who underwent multimodal neuromonitoring (including NIRS and TCD), were included. rSO_2 and its components [relative changes in O_2Hbi, HHbi, and total haemoglobin (cHbi)] were compared with TCD (cerebral blood flow velocity, CBFV). Changes (Δ) in CBFV and rSO_2, ΔO_2Hbi, ΔHHbi, and ΔcHbi after systemic arterial blood pressure (MAP) modifications induced by different manoeuvres (e.g., rescue therapies and haemodynamic manipulation) were assessed using mixed-effect linear regression analysis and repeated measures correlation coefficients. All values were normalised as percentage changes from the baseline (Δ%).

Results

One hundred and four measurements from 25 patients were included. Significant effects of Δ%MAP on Δ%CBF were observed after rescue manoeuvres for CBFV, ΔcHbi, and ΔO_2Hbi. The highest correlation was found between ΔCBFV and $\Delta\Delta O_2Hbi$ ($R = 0.88$, $p < 0.0001$), and the poorest between ΔCBFV and ΔΔHHbi ($R = 0.34$, $p = 0.002$).

Conclusions

ΔO_2Hbi had the highest accuracy to assess CBF changes, reflecting its role as the main component for vasomotor response after changes in MAP. The use of indexes derived from the different components of rSO_2 can be useful for the bedside evaluation of cerebral haemodynamics in mechanically ventilated patients with COVID-19.

Correlation of cerebrovascular resistance index (CVRi) and cerebrovascular conductance index (CVCi) for cerebral blood flow velocity (CBFV) and NIRS parameters.

	$\Delta CVRi_{CBFV}$	*p*-value		$\Delta CVCi_{CBFV}$	*p*-value
$\Delta CVRi_{rSO_2}$	0.99 (0.99-0.99)	**<0.0001**	$\Delta CVCi_{rSO_2}$	0.8 (0.71-0.81)	**<0.0001**
$\Delta CVRi_{\Delta cHbi}$	0.17 (-0.05-0.38)	0.12	$\Delta CVCi_{\Delta cHbi}$	0.62 (0.47-0.74)	**<0.0001**
$\Delta CVRi_{\Delta O2Hbi}$	0.28 (0.06-0.47)	**0.01**	$\Delta CVCi_{\Delta O2Hbi}$	0.71 (0.58-0.80)	**<0.0001**
$\Delta CVRi_{\Delta HHbi}$	0.01 (-0.22-0.23)	0.95	$\Delta CVCi_{\Delta HHbi}$	0.32 (0.11-0.51)	**0.004**

CBFV, cerebral blood flow velocity; CI, confidence interval; ΔcHbi, sum of ΔO_2Hbi and ΔHHbi components of the regional tissue oxygen saturation; ΔO_2Hbi, index representing the change in the oxyhemoglobin of the regional tissue oxygen saturation; ΔHHb, index representing the change in the deoxyhemoglobin of the regional tissue oxygen saturation; rSO_2, regional cerebral oxygenation.

110 Early Effects of Ventilatory Rescue Therapies on Systemic and Cerebral Oxygenation in Mechanically Ventilated COVID-19 Patients with Acute Respiratory Distress Syndrome: A Prospective Observational Study

Robba C, Ball L, Battaglini D, Cardim D, Moncalvo E, Brunetti I, Bassetti M, Giacobbe DR, Vena A, Patroniti N, Rocco PRM, Matta BF, Pelosi P; collaborators. *Crit Care*. 2021 Mar 19;25(1):111.

Background

In COVID-19 patients with acute respiratory distress syndrome (ARDS), the effectiveness of ventilatory rescue strategies remains uncertain, with controversial efficacy on systemic oxygenation and no data available regarding cerebral oxygenation and hemodynamics.

Methods

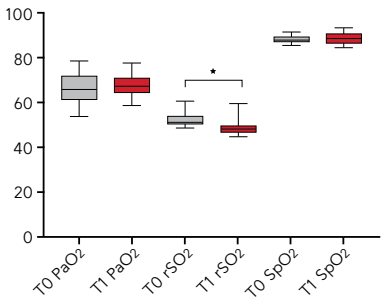
This is a prospective observational study conducted at San Martino Policlinico Hospital, Genoa, Italy. We [study investigators] included adult COVID-19 patients who underwent at least one of the following rescue therapies: recruitment maneuvers (RMs), prone positioning (PP), inhaled nitric oxide (iNO), and extracorporeal carbon dioxide (CO_2) removal ($ECCO_2R$). Arterial blood gas values (oxygen saturation [SpO_2], partial pressure of oxygen [PaO_2] and of carbon dioxide [$PaCO_2$]) and cerebral oxygenation (rSO_2) were analyzed before (T0) and after (T1) the use of any of the aforementioned rescue therapies. The primary aim was to assess the early effects of different ventilatory rescue therapies on systemic and cerebral oxygenation. The secondary aim was to evaluate the correlation between systemic and cerebral oxygenation in COVID-19 patients.

Results

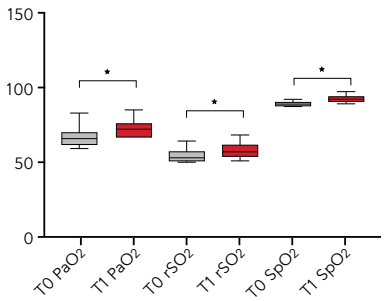
Forty-five rescue therapies were performed in 22 patients. The median [interquartile range] age of the population was 62 [57-69] years, and 18/22 [82%] were male. After RMs, no significant changes were observed in systemic PaO_2 and $PaCO_2$ values, but cerebral oxygenation decreased significantly (52 [51-54]% vs. 49 [47-50]%, $p < 0.001$). After PP, a significant increase was observed in PaO_2 (from 62 [56-71] to 82 [76-87] mmHg, $p = 0.005$) and rSO_2 (from 53 [52-54]% to 60 [59-64]%, $p = 0.005$). The use of iNO increased PaO_2 (from 65 [67-73] to 72 [67-73] mmHg, $p = 0.015$) and rSO_2 (from 53 [51-56]% to 57 [55-59]%, $p = 0.007$). The use of $ECCO_2R$ decreased PaO_2 (from 75 [75-79] to 64 [60-70] mmHg, $p = 0.009$), with reduction of rSO_2 values (59 [56-65]% vs. 56 [53-62]%, $p = 0.002$). In the whole population, a significant relationship was found between SpO_2 and rSO_2 ($R = 0.62$, $p < 0.001$) and between PaO_2 and rSO_2 (R0 0.54, $p < 0.001$).

Conclusion

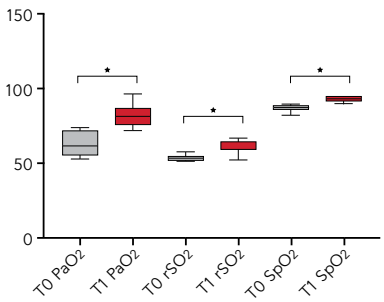
Rescue therapies exert specific pathophysiological mechanisms, resulting in different effects on systemic and cerebral oxygenation in critically ill COVID-19 patients with ARDS. Cerebral and systemic oxygenation are correlated. The choice of rescue strategy to be adopted should take into account both lung and brain needs. Registration The study protocol was approved by the ethics review board (Comitato Etico Regione Liguria, protocol n. CER Liguria: 23/2020).



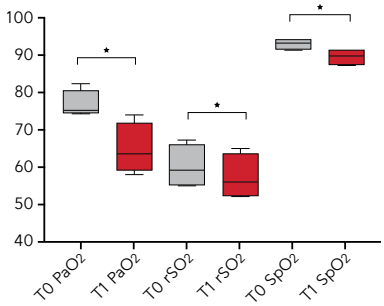
Boxplots representing the effect of recruitment maneuvers (RMs) on partial pressure of oxygen (PaO_2), cerebral oxygenation (rSO_2), and oxygen saturation (SpO_2) from baseline, T0 (pre), and after RMs, T1 (post). Values are presented as median and interquartile range



Boxplots representing the effect of inhaled nitric oxide (iNO) on partial pressure of oxygen (PaO_2), cerebral oxygenation (rSO_2), and oxygen saturation (SpO_2) from baseline, T0 (pre), and after iNO, T1 (post). Values are presented as median and Interquartile range



Boxplots representing the effect of prone positioning onpartial pressure of oxygen (PaO_2), cerebral oxygenation (rSO_2), and oxygen saturation (SpO_2), from baseline, T0 (pre), and after prone positioning, T1 (post). Values are presented as median and interquartile range



Boxplots representing the effect of $ECCO_2R$ or respiratory dialysis on partial pressure of oxygen (PaO_2), cerebral oxygenation (rSO_2), and oxygen saturation (SpO_2) from baseline, T0 (pre), and after CO_2 removal, T1 (post). Values are presented as median and interquartile range

06: Capnography

111 Correlation of End-Tidal Carbon Dioxide Tension with Arterial Carbon Dioxide Tension in Patients with Respiratory Failure on Mechanical Ventilation

Hamdy Zoair, Ahmed Ewis, Islam Ezzat. *The Egyptian Journal of Hospital Medicine*. 2019;74(8): 1902-1906.

Background

Patients undergo mechanical ventilation need continuous evaluation of their respiratory condition. Monitoring of end-tidal carbon dioxide ($EtCO_2$) as noninvasive measurement of arterial carbon dioxide ($PaCO_2$) is a good tool for assessment and management of mechanically ventilated patients.

Aim of the Work

The aim of this work is to correlate expiratory end-tidal carbon dioxide tension with arterial carbon dioxide tension in patients with respiratory failure on mechanical ventilation and its significance.

Patients and Methods

This study was carried out on 50 patients on invasive mechanical ventilation with acute or acute on top of chronic respiratory failure admitted to respiratory I.C.U. at Bab El- Shaeria University Hospital, Studied patients had obtained two ABG samples one at the onset of mechanical ventilation(M.V.) and the second when the patient was on weaning mode of mechanical ventilation with continuous capnographic monitoring and reading record at the onset of ABG sampling.

Results

The study include 31 males (62%), and 19 female (38%), 24 patients (48%) had C.O.P.D, 9 patients (18%) had pneumonia, 8 patients (16%) had O.H.S, 7 patients (14%) had I.L.D and 2 patients (4%) had acute severe asthma. The study shows no statistical significant difference between $PaCO_2$ and $EtCO_2$ at the onset of mechanical ventilation (74.78 ± 20.19 and 67.5 ± 19.23) mmHg and on weaning mode (43.98 ± 8.07 and 42.2 ± 7.2) mmHg. that $PaCO_2$ measurements vary approximately 2-7 mmHg above $EtCO_2$ values which mean good correlation between $PaCO_2$ and $EtCO_2$.

Conclusion

$EtCO_2$ measurement provides an accurate estimation of $PaCO_2$ in ventilation and weaning which may reduce the need for invasive, high coast monitoring and repeated arterial blood gas analyses.

Comparison between $PaCO_2$ and $EtCO_2$ at M.V. onset and weaning mode.

CO_2 Variables		$PaCO_2$ (N = 50)	$EtCO_2$ (N = 50)	P-value
CO_2 (mmHg) M.V.	Mean	74.78	67.5	0.06
	±SD	20.19	19.23	
CO_2 (mmHg) Weaning	Mean	43.98	42.2	0.3
	±SD	8.07	7.2	

112 Availability of Portable Capnometers in Children with Tracheostomy

Hotta M, Hirata K, Nozaki M, Mochizuki N, Hirano S, Wada K. *Pediatr Int*. 2021 Jul;63(7):833-837.

Background

A capnometer is a noninvasive monitor that is used to assess patients' respiratory status. This study was performed to evaluate the availability of a portable capnometer in children with tracheostomy.

Methods

This retrospective study included children with tracheostomy who were treated at the Osaka Women's and Children's Hospital Osaka, Japan, from 1 September 2018 to 31 October 2019. We [study investigators] assessed the correlation between the partial pressure of venous carbon dioxide ($PvCO_2$) and end-tidal carbon dioxide tension ($EtCO_2$) using a portable capnometer (EMMA; Masimo, Irvine, CA, USA).

Results

Nine infants and 43 simultaneous $PvCO_2$-$EtCO_2$ pairs were analyzed. The correlation coefficient of these pairs was 0.87 (95% confidence interval, 0.77-0.93; $P < 0.001$). The Bland-Altman plot showed that $EtCO_2$ was on average 10.0 mmHg lower than its paired $PvCO_2$ value (95% limits of agreement, 1.0-19.1). The difference between $PvCO_2$ and $EtCO_2$ was significantly greater in patients on ventilators.

Conclusion

The portable capnometer evaluated in this study (EMMA) was readily available and useful for assessment of the respiratory condition in children with tracheostomy.

Relationship of study factors with difference between $PvCO_2$ and $EtCO_2$

Cannula Size	Average of difference ($PvCO_2$–$EtCO_2$), mmHg	Standard deviation	p value
3.0mm	10.8	9.9	0.36
3.5mm	7.8	5.7	
4.0mm	11.6	4.2	
5.0mm	7.1	NA	

(by one-way analysis of variance)

	Correlation coefficient	p value
Age	0.34	0.028
Body weight	0.34	0.025

(by Spearman's rank correlation coefficient)

NA, not applicable; $PvCO_2$, partial pressure of venous carbon dioxide; $EtCO_2$, end-tidal carbon dioxide tension

07: High-Flow Nasal Oxygen Therapy

113 Nasal High-flow Versus Noninvasive Ventilation in Patients with Chronic Hypercapnic COPD

Bräunlich J, Dellweg D, Bastian A, Budweiser S, Randerath W, Triché D, Bachmann M, Kähler C, Bayarassou AH, Mäder I, Geiseler J, Köhler N, Petroff D, Wirtz H. *Int J Chron Obstruct Pulmon Dis*. 2019 Jul 5;14:1411-1421.

Background

Despite the encouraging results of noninvasive ventilation (NIV) in chronic hypercapnic COPD patients, it is also evident that some patients do not tolerate NIV or do not benefit from it. We [investigators] conducted a study in which COPD patients with stable, chronic hypercapnia were treated with NIV and nasal high-flow (NHF) to compare effectiveness.

Methods

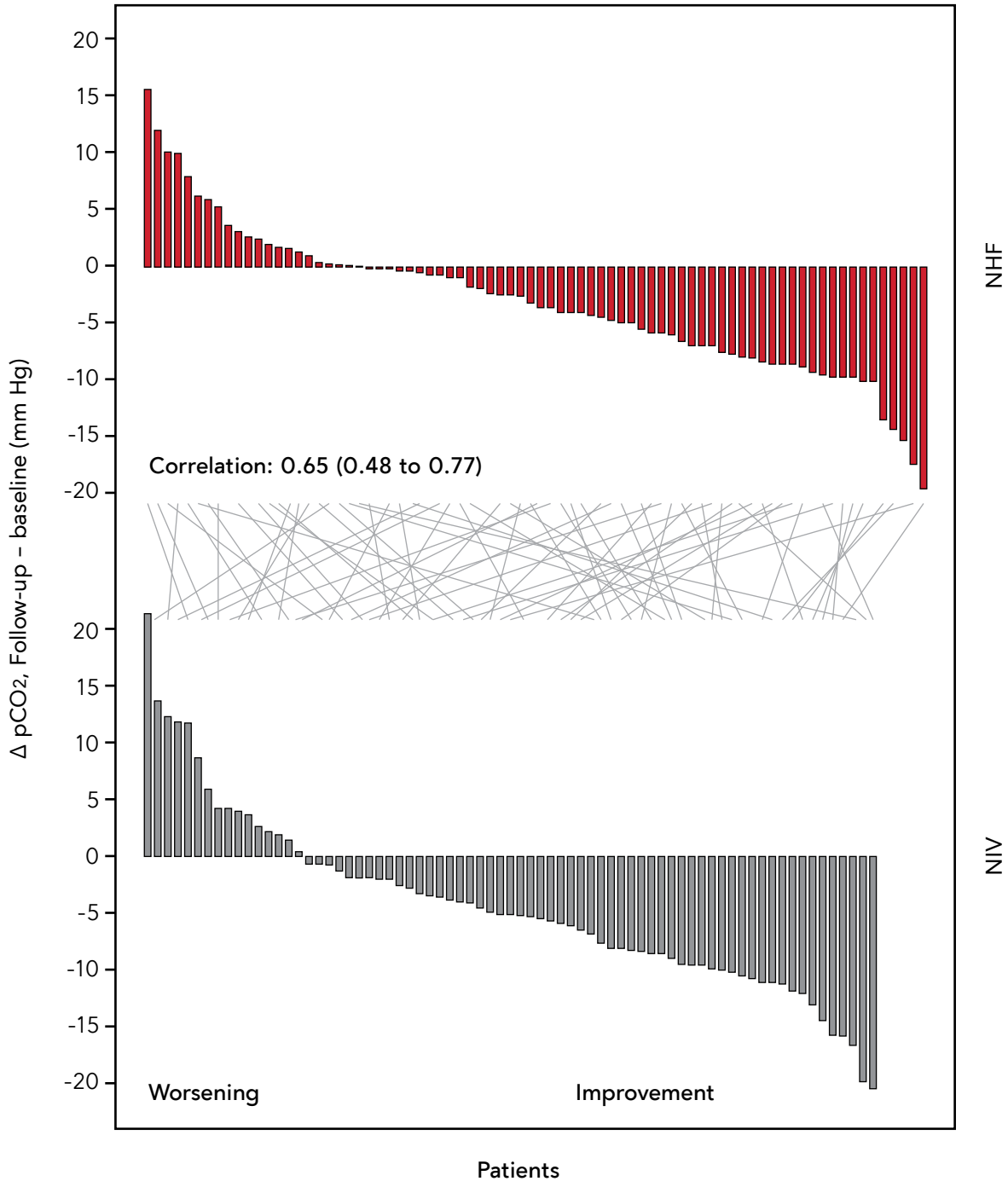
In a multi-centered, randomized, controlled, cross-over design, patients received 6 weeks of NHF ventilation followed by 6 weeks of NIV ventilation or vice-versa (TIBICO) between 2011 and 2016. COPD patients with stable daytime hypercapnia ($pCO_2 \geq 50$ mmHg) were recruited from 13 German centers. The primary endpoint was pCO_2 changes from baseline blood gas, lung function, quality of life (QoL), the 6 min walking test, and duration of device use were secondary endpoints.

Results

A total of 102 patients (mean±SD) age 65.3±9.3 years, 61% females, body mass index 23.1±4.8 kg/m2, 90% GOLD D, pCO_2 56.5±5.4 mmHg were randomized. PCO_2 levels decreased by 4.7% (n=94; full analysis set; 95% CI 1.8-7.5, P=0.002) using NHF and 7.1% (95% CI 4.1-10.1, P<0.001) from baseline using NIV (indistinguishable to intention-to-treat analysis). The difference of pCO_2 changes between the two devices was -1.4 mmHg (95% CI -3.1-0.4, P=0.12). Both devices had positive impact on blood gases and respiratory scores (St. George's Respiratory Questionnaire, Severe Respiratory Insufficiency Questionnaire).

Conclusion

NHF may constitute an alternative to NIV in COPD patients with stable chronic hypercapnia, eg, those not tolerating or rejecting NIV with respect to pCO_2 reduction and improvement in QoL.



Notes: NHF, nasal high-flow; NIV, noninvasive ventilation. ΔpCO_2 is the difference in partial pressures of carbon dioxide in capillary blood between baseline and follow-up. Each bar represents ΔpCO_2 for a single patient and the grey lines show how the patients in the upper and lower halves correspond, ie, the grey line connects a given patient before and after cross-over. The correlation coefficient between changes with NHF and NIV (95% CI) is shown for patients that used both devices.

Waterfall plot depicting the individual change in carbon dioxide levels in capillary blood (pCO_2) before and after intervention.

07: High-Flow Nasal Oxygen Therapy – softFlow

114 Nasal High-flow in Acute Hypercapnic Exacerbation of COPD

Bräunlich J, Wirtz H. *Int J Chron Obstruct Pulmon Dis*. 2018 Nov 30;13:3895-3897.

Introduction

Since the late 1980s non-invasive ventilatory support (NIV) has become a standard treatment in acute exacerbation of COPD (AECOPD) with hypercapnia.[1] Although NIV has been shown to be extremely useful in this situation, but up to 30% of hypercapnic AECOPD patients do not tolerate NIV for several reasons.[2]

Methods

Thirty-eight patients were treated between 2015 and 2017 at the Department of Respiratory Medicine, University hospital Leipzig, Germany. Patients were included if they a) did not tolerate NIV following a regular trial (intolerance of NIV), b) fulfilled AECOPD criteria (Anthonisen), c) had a decrease in pH (pH #7.38) and a capillary $paCO_2$ >45 mmHg at admission, d) had absence of acute metabolic disorders, and e) did not fulfill criteria for intubation. Initiation of NHF (Softflow 50; TNI medical AG, Würzburg) was titrated to achieve a flow rate with greatest tolerability. Oxygen flow (as part of the total flow) was then adjusted to achieve baseline SpO_2 values. Changes in partial pressures of oxygen (paO_2) and $paCO_2$ as well as pH in capillary blood gas analysis were monitored closely. NHF was terminated when pH increased to more than 7.38 or when the patient no longer tolerated the device or had lesser symptoms. Statistical analysis was performed using an ANOVA test (Sigma Plot; Systat Software GmbH, Ekrath, Germany). This study was approved by the University of Leipzig ethics committee (110/18-ek) and registered (NCT03523481). Patients provided written informed consent. The study was carried out in accordance with the principles of the Declaration of Helsinki.

Results

A significant treatment effect was seen in mean capillary blood pH and in mean $paCO_2$ (Table 1). Greatest improvements in pH and $paCO_2$ were found in 17 patients with baseline pH ,7.35 (Table 1).

Conclusion

To our [investigators'] knowledge, this is the first observation evaluating NHF in a cohort with solely hypercapnic (partly acidotic) AECOPD patients. We [study investigators] found significant improvements of pH and $paCO_2$. Our [investigators'] study demonstrates that using NHF in severe-to-moderate acidotic and non-acidotic hypercapnic AECOPD patients who did not tolerate NIV is useful. The limitation of this investigation is best described by its retrospective nature with the lack of a control group. The number of patients was low but appears to be sufficient for a first answer as to whether NHF may be useful in hypercapnic AECOPD patients.

Parameters during NHF treatment

Parameters	All patients (pH ≤7.38; n=38)			
	Baseline (mean±SD)	End (mean±SD)	Change (mean±SD)	*P*-value
pH	7.339±0.041	7.392±0.048	0.052±0.048	0.000
pCO_2 mmHg	67.6±12.9	58.5±9.7	-9.1±8.8	0.001
pO_2 mmHg	58.3±15.2	58.3±17.6	–	0.983
SO_2 %	85.3±9.5	86.2±11.3	–	0.798
HCO_3 mmol/L	30.8±5.1	31.6±5.3	–	0.636
Base excess mmol/L	6.9±4.9	7.7±5.4	–	0.633
NHF flow L/min	–	25.8±8.2	–	–
Treatment time min	–	195±231	–	–
	Patients with pH <7.35 (n=17)			
pH	7.298±0.046	7.379±0.051	0.082±0.060	0.000
pCO_2 mmHg	73.7±13.7	59.6±11.2	-14.2±10.6	0.002
pO_2 mmHg	56.9±14.8	55.6±20.7	–	0.845
SO_2 %	84.8±10.1	84.3±11.9	–	0.904
HCO_3 mmol/L	31.6±5.5	32.5±5.6	–	0.661
Base excess mmol/L	7.4±5.3	8.5±5.7	–	0.591
NHF flow L/min	–	26.3±7.9	–	–
Treatment time min	–	252±251	–	–

Notes: Changes in blood gas analyses data, usage time and flow rates during NHF therapy in all patients and in the subgroup with pH <7.35. All data are organized as mean±SD. "–" indicates no significant differences to report.
Abbreviation: NHF, nasal high-flow.

115 Nasal Highflow Improves Ventilation in Patients With COPD

Bräunlich J, Köhler M, Wirtz H. *Int J Chron Obstruct Pulmon Dis*. 2016 May 25;11:1077-85.

Background

Nasal highflow (NHF) provides a warmed and humidified air stream up to 60 L/min. Recent data demonstrated a positive effect in patients with acute hypoxemic respiratory failure, especially when caused by pneumonia. Preliminary data show a decrease in hypercapnia in patients with COPD. Therefore, NHF should be evaluated as a new ventilatory support device. This study was conducted to assess the impact of different flow rates on ventilatory parameters in patients with COPD.

Materials and Methods

This interventional clinical study was performed with patients suffering from severe COPD. The aim was to characterize flow-dependent changes in mean airway pressure, breathing volumes, breathing frequency, and decrease in partial pressure of CO_2 (pCO_2). Mean airway pressure was measured in the nasopharyngeal space (19 patients). To evaluate breathing volumes, we [study investigators] used a polysomnographic device (18 patients). All patients received 20 L/min, 30 L/min, 40 L/min, and 50 L/min and - to illustrate the effects - nasal continuous positive airway pressure and nasal bilevel positive airway pressure. Capillary blood gas analyses were performed in 54 patients with hypercapnic COPD before and two hours after the use of NHF. We [study investigators] compared the extent of decrease in pCO_2 when using 20 L/min and 30 L/min. Additionally, comfort and dyspnea during the use of NHF were surveyed.

Results

NHF resulted in a minor flow dependent increase in mean airway pressure. Tidal volume increased, and breathing rate decreased. The calculated minute volume decreased under NHF breathing. In spite of this fact, hypercapnia decreased with increasing flow (20 L/min vs 30 L/min). Additionally, an improvement in dyspnea was observed. The rapid shallow breathing index shows a decrease when using NHF.

Conclusion

NHF leads to a flow-dependent reduction in pCO_2. This is most likely achieved by a washout of the respiratory tract and a functional reduction in dead space. In summary, NHF enhances effectiveness of breathing in patients with COPD, reduces pCO_2, the work of breathing, and rapid shallow breathing index as an indicator of respiratory work load.

Fig. 1

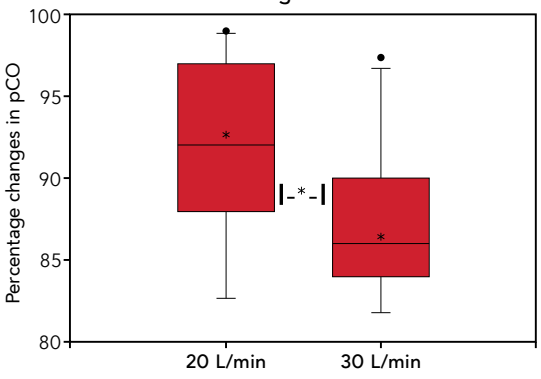


Fig. 2

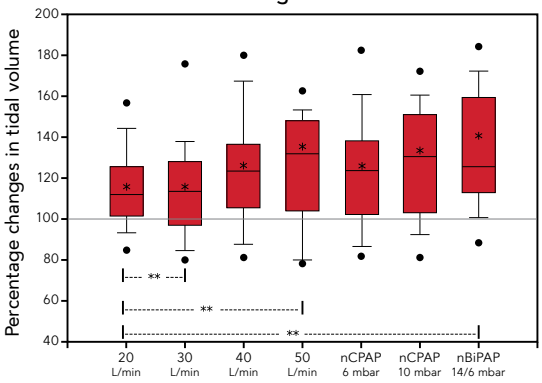


Fig. 3

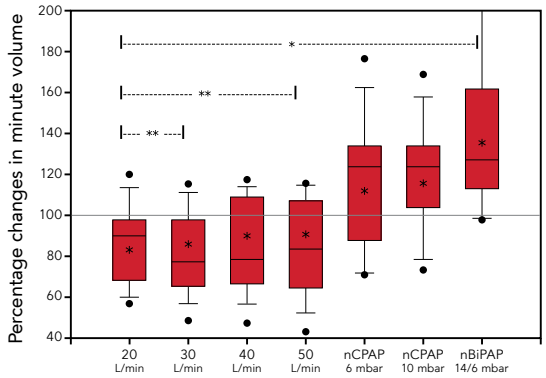


Figure 1. Percentage changes in pCO_2 after 2 hours of NHF breathing (n=54, medium prong size).

Figure 2. Percentage changes in tidal volume (n=18, medium prong size).

Figure 3. Percentage changes in minute volume (n=18, medium prong size).

Notes: *Significant *P*-value and **no significant *P*-value.

Abbreviations: NHF, nasal highflow; pCO_2, partial pressure of CO_2; nBiPAP, (nasal) bilevel positive airway pressure; nCPAP, (nasal) continuous positive airway pressure.

Masimo U.S.
Tel: 1 877 4 Masimo
info-america@masimo.com

Masimo International
Tel: +41 32 720 1111
info-international@masimo.com

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