Meta-analysis of arterial oxygen saturation monitoring by pulse oximetry in adults

Louise A. Jensen, RN, PhD, Judee E. Onyskiw, RN, PhD(c), and N.G.N. Prasad, PhD
Edmonton, Alberta, Canada

OBJECTIVE: The purposes of the study were to: (1) describe the aggregate strength of the relationship of arterial oxygen saturation as measured by pulse oximetry with the standard of arterial blood gas analysis as measured by co-oximetry, (2) examine how various factors affect this relationship, and (3) describe an aggregate estimate of the bias and precision between oxygen saturation as measured by pulse oximetry and the standard in vitro measures.

DESIGN: A meta-analysis was conducted.

SAMPLE: Seventy-four studies from 1976 to 1994 met the inclusion criteria of: (1) adult study population, (2) quantitative analysis of empirical data, and (3) bivariate correlations or bias and precision estimates between pulse oximeter and co-oximeter values.

RESULTS: There were a total of 169 oximeter trials on 41 oximeter models from 25 different manufacturers. Studies were conducted in various settings with a variety of subjects, with most being healthy adult volunteers. The weighted mean r, based on 39 studies (62 oximeter trials) for which the r statistic and number of data points were available, was 0.895 (var [r] = 0.014). Based on 23 studies (82 oximeter trials) for which bias and precision estimates and number of data points were available, the mean absolute bias and precision were 1.999 and 0.233, respectively. Several factors were found to affect the accuracy of pulse oximetry.

CONCLUSION: Pulse oximeters were found to be accurate within 2% (± 1 SD) or 5% (± 2 SD) of in vitro oximetry in the range of 70% to 100% Sao_2. In comparing ear and finger probes, readings from finger probes were more accurate. Pulse oximeters may fail to record accurately the true Sao_2 during severe or rapid desaturation, hypotension, hypothermia, dyshemoglobinemia, and low perfusion states.
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The availability of oxygen, its transport and extraction at the tissue level, are vital factors to consider in caring for the acutely ill patient.[1,2] The amount of oxygen reversibly bound to hemoglobin in arterial blood is referred to as the percentage of oxygen saturation of hemoglobin (Sao_2). Because Sao_2 determines the majority of oxygen content, it is considered to be a clinically significant index of oxygenation.[3] Although arterial blood gas (ABG) analysis by co-oximetry has been the gold standard for measuring arterial oxygen saturation, it is invasive, involves repeated sampling of arterial blood, is costly, is time consuming, gives information only intermittently, and imposes a delay between sampling and the availability of results.

Noninvasive assessment of Sao_2 has been made possible and simple by pulse oximetry. Measurement of oxygen saturation with use of the light absorption properties of hemoglobin was first proposed in the 1930s.[4] Pulse oximetry evolved from 3 technologies: oximetry, plethysmography, and microprocessor-based instrumentation.[5] A detailed history of the origins of this technique has been presented by Severinghaus and Astrup,[6,7] and Severinghaus and Honda.[8] Matthes in 1936 is

From the Faculty of Nursing and the Department of Mathematical Sciences, the University of Alberta, Edmonton, Alberta.

Reprint requests: Louise A. Jensen, RN, PhD, Professor, Faculty of Nursing, University of Alberta, 3rd Floor, Clinical Sciences Building, Edmonton, Alberta, T6G 2G3.

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credited with developing the first oximeter to continuously monitor oxygen saturation with 2 wavelengths of light.[7] This bulky, impractical sensor was later replaced in the 1940s by Millikan with a lightweight ear sensor designed for aviators,[5] and by Squire with a sensor applied to the web of the hand.[9] Despite further refinements, oximeters were still awkward: difficult to use and to calibrate. Then in 1950, the development of the Clark polarographic electrode for measuring oxygen tension in blood samples led to a decline of interest in oximetry.[2] Interest in oximetry was renewed in the 1960s when Hewlett-Packard produced the first commercial ear oximeter (HP 47201A). Featuring precalibration and a fixed path length, this oximeter solved many of the earlier problems. A major advance came in 1971 when Takuo Aoyagi led the way in the development of pulse oximetry based on pulsatile signals. This new concept took commercial form in the Minolta Oximeter.[10] Next, Ohmeda BIOX and Nellcor ushered in a new era of microprocessor-based devices that were smaller and more convenient to use.[5]

Measurement of oxygen saturation with use of optical techniques is based on the Beer-Lambert law[4,11] that, "in order to determine the relative absorbance for each of a number of solutes, the transmission of an equal number of light wavelengths through the solution must be measured."[12,p.45] Pulse oximetry combines the principles of spectrophotometry and plethysmography. Pulse oximeters measure the absorption of specific wavelengths of light in oxygenated hemoglobin as compared with that of reduced hemoglobin.[1-4,13,14] A probe, which can be clip-on or adhesive, reusable or disposable, is placed on a finger, ear lobe, nose, or a site with an adequate pulsating vascular bed. One side of the probe has 2 light-emitting diodes (LED) that transmit light wavelengths through pulsating arterial blood to a photodetector on the other side of the probe.[2-4,13-15] One LED transmits infrared light (900 to 940 nm), which is absorbed by the oxyhemoglobin. The other wavelength emits red light (660 nm), which is absorbed by the reduced hemoglobin (deoxyhemoglobin). Pulsatile arterial blood during systole causes an influx of oxyhemoglobin to the tissue, absorbing more infrared light, thus allowing less light to reach the photodetector. Changes in optical density associated with systole become the basis for calculation of arterial oxygen saturation.[2] The amplitude of light transmitted depends on the size of the arterial pulse change, the wave length of light used, and oxygen saturation of hemoglobin.[16,17] The microprocessor processes or filters the signals received and provides a digital display of O_2 saturation, symbolized by Spo_2.

Pulse oximetry remained a research tool for several years before clinical use began in the early 1980s.[18] New[19] and others,[5-9,15,18,20-32] have reviewed the literature on measuring arterial oxygen saturation by pulse oximetry. Technical advancements over recent years have refined pulse oximeters. Most pulse oximeters now provide a visual digital and waveform display, an audible display of arterial pulsations and heart rate, and a variety of sensors to accommodate individuals regardless of age, size, or weight.[33] Consequently, pulse oximetry is used for continuous monitoring of arterial oxygen saturation in a variety of settings. It is now standard care in the operating room,[4,13,14,34-37] in transfer from the operating room,[2,34,38] in the postanesthesia care unit,[2,4,39-49] in the critical care unit,[2,4,27,50-56] for ventilatory management,[57-59] and during various diagnostic and interventional procedures.[2,34,58,60-66] Pulse oximetry also is used in the emergency department for a variety of situations,[3,17,67-70] such as during respiratory dysfunction, minor surgical procedures, treatments, or medication administration. Other settings that use pulse oximetry are pulmonary function testing laboratories[9,71] and research laboratories for sleep apnea[72-74] and exercise.[75-77] Pulse oximetry is also used for periodic checks on medical and surgical units and in the labor and delivery unit.[4,32] Emergency medical services also use pulse oximetry in the prehospital care setting.[12,78,79] It is used in the field where assessment time is limited and resources are few.[80] Pulse oximetry is also being evaluated for monitoring respiratory function in patients at home.[9,81,82]

Accuracy and Precision of Pulse Oximetry

The degree of accuracy between pulse oximetry and in vitro methods was first reported in the literature as a correlation coefficient. Subsequently, Bland and Altman[83] criticized the use of the correlation coefficient solely as a measure of agreement in determining accuracy, as the correlation procedures reflect only the relationship between 2 measures and may be influenced by variation between individuals. Bias and precision estimates then became the standard reported statistic when comparing the 2 methods. The bias, or systematic error, indicates the overestimation or underestimation of 1 method relative to the other; whereas the precision represents the variability or random error. Bias

is estimated by the mean difference between the 2 measures and the precision by the standard deviation of the mean difference.[83]

Pulse oximetry has been reported to be accurate within 5% ± 2% of in vitro oximetry.[12] Pulse oximeters are most accurate in the 70% to 100% saturation range, where readings usually vary no more than 1% to 2% from the measurements obtained by standard blood gas analysis.[9] Huffman[13] stated that in the 80% to 100% Sao_2 range, a tolerance of ± 2% has become the accepted standard of performance. Although pulse oximetry is considered sufficiently accurate for many clinical purposes, there are limitations. Mengelkoch et al[15] and Gaskin and Thomas[31] reviewed studies that assessed the accuracy of pulse oximeters during exercise and concluded that pulse oximetry accuracy was variable, even among the same models. Thus comparing different models of pulse oximeters may be irrelevant if the internal algorithms differ.[13] A single pulse oximeter cannot be considered a representative sample for that model, yet ranking accuracy of different pulse oximeters does not dismiss the efficacy of a particular pulse oximeter.[13]

Although most difficulties that result when using pulse oximeters produce a blank screen or an error message, some circumstances do produce false readings (Table I).[84] One limitation of pulse oximetry involves the arterial concentrations of carboxyhemoglobin (CoHb) and methemoglobin (MetHb).* Carboxyhemoglobin and MetHb have light absorption characteristics similar to oxyhemoglobin that can falsely elevate Spo_2 levels.[15,33,87]

Intravenous dyes used in diagnostic and hemodynamic testing also can cause inaccurate (usually lower) estimates of Spo_2.† Furthermore, Gramlich,[33] Durren,[67] the American Association for Respiratory Care (AARC),[81] and Cahan et al[91] suggested that the signal quality and the accuracy of Spo_2 measurements are significantly affected in people with deeply pigmented skin. Yet, Mardirossian and Schneider[14] and Bothma et al[92] contend that pulse oximetry is not affected by racial skin pigmentations. Another source of error affecting pulse oximetry accuracy may be jaundice or bilirubin levels higher than 20 mg/dL.[14,17,78] On the other hand, Durren,[67] the AARC,[81] and Chelluri et al[93] reported that hyperbilirubinemia was not found to alter Spo_2 estimates when the oxygen saturation was more than 90%. Finally, Coté et al[94] found that brown-red nail polish interfered with pulse oximetry and should be removed before monitoring.

Table I
Factors affecting accuracy of pulse oximetry

Sources of error	Effects on Spo_2
CoHb	Overestimation
Methemoglobinemia	Underestimation
Methylene blue	Underestimation
Skin pigmentation	Signal loss, underestimation
Hyperbilirubinemia	Overestimation
Hypoxemia	Magnifies error
Reduced perfusion	Signal loss, underestimation
Reduced vascular pulsations	Underestimation
Anemia	Underestimation
Motion artifact	Signal loss, underestimation
Ambient light	Underestimation

Two characteristics of pulse oximeters may cause errors in Spo_2 estimates during hypoxic conditions. Algorithms used in pulse oximeters incorporate calibration curves derived from studies in which subjects' arterial oxygen saturation levels are ≥ 70%. Also, during hypoxic conditions, the level of reduced hemoglobin is greater, which can magnify the error in the absorption ratio.[15] Fanconi[95] reviewed the use of pulse oximeters during episodes of hypoxemia in 9 studies and found mixed results. Overall, few pulse oximeters performed well at oxygen saturation levels of less than 70%.[96-98] As well, the Technology Assessment Task Force of the Society of Critical Care Medicine,[34] and the AARC[81] suggested that for Sao_2 levels less than 80%, oximetry readings are less accurate because the oxyhemoglobin and deoxyhemoglobin are more similar in color at that level of saturation.

When peripheral tissue is poorly perfused, the signal from the pulsatile flow of blood will be impaired. Thus, if a peripheral pulse is absent (cardiac arrest) or of low amplitude (hypovolemia, hypotension, hypothermia, peripheral edema, alpha-adrenergic infusions, cardiogenic shock, or cardiac bypass), pulse oximetry readings will be intermittent or unavailable.‡

Non-arterial pulses can also be detected, for example if the probe is secured too tightly, creating venous pulsations in the finger.[78] Other situations

*3,11,12,14,15,17,33,67,81,85,86

† 3,14,17, 18,67,81,88-90

‡ 12,14,15,17,18,24,33,67,78,81,99-109

increasing venous pulsations are right-sided heart failure, tricuspid regurgitation, high positive end expiratory pressure, or the tourniquet effect of a blood pressure cuff above the probe.[2,4,110] Barker et al[97] also found that calibration curves of the pulse oximeters studied were changed greatly by sensor malpositioning. At low Sao_2 values, only mild hypoxemia was indicated when, in fact, hypoxemia was profound.

There is some evidence that severe anemia affects pulse oximetry accuracy.[111,112] An increased bias in both anemic and nonanemic subjects as the level of hypoxemia increases has been reported, but the error was greatest in anemic subjects with hemoglobin levels below 5 g/dL.[4,111-113] The cause of the additional error due to anemia is not fully known, but may be due to photon scattering of light and a shift in red-light wavelength increasing its absorption.[15]

Another commonly encountered problem with pulse oximeters is motion artifact.[§] Although some pulse oximeters are designed to compensate for motion artifact,[116] it may result in a falsely low reading or signal loss. Occasionally, false pulse oximeter values are produced when there are significant amounts of ambient light on the sensor probe,[‖] such as sunlight, fluorescent lights, xenon lamps, surgical lamps, and infrared heating lamps. Finally, Schnapp and Cohen,[4] and Mardirossian and Schneider[14] reported that 60-cycle interference caused by activated cautery tools renders pulse oximeters ineffective, displaying erroneous oxygen saturation values and sounding false alarms. Ralston et al[119] found that 6 of 13 units tested gave erroneous readings, with no clear warning that the signal was unsatisfactory.

Purpose of the Study

There has been a rapid acceptance of pulse oximetry as a mode of monitoring patients in clinical settings with a consequent proliferation of manufacturers and models. Although there have been several integrative reviews on the accuracy of pulse oximetry, no meta-analysis of this data has been conducted. The purposes of this study were to: (1) describe the aggregate strength of the relationship of Sao_2 as measured by pulse oximetry with the standard of ABG analysis as measured by co-oximeter, (2) examine how various factors affected this relationship, and (3) describe an aggregate estimate of the bias and precision between oxygen saturation as measured by pulse oximetry and the standard in vitro measures.

METHOD

Sample. Published English articles on pulse oximetry were located by searching the computerized and citation indexes of literature in the health science disciplines. MEDLINE, EMBASE, HEALTHSTAR, and CINAHL databases were searched from 1970 to 1995. Bibliographies also were reviewed to locate any studies not identified in the computerized searches. Published abstracts were retrieved when a published report was not found after a search of the author's(s') name(s). Each retrieved study was assessed independently by 2 investigators for inclusion, and 100% agreement was needed for inclusion in the final corpus of studies. Inclusion criteria were (1) quantitative analysis of empirical data, (2) bivariate correlations and/or bias and precision estimates between pulse oximeter and co-oximeter value estimates, and (3) adult population.

Procedure. An instrument was developed to rate scientific merit, because existing scales were inadequate for evaluating descriptive measurement studies (Table II). Assessment criteria included adequacy of measurement of the predictor (pulse oximeter) and criterion (co-oximeter) variables, and quality of the method, sample, and data analysis techniques. Twelve quality assessment criteria were rated on a 3-point scale (ie, acceptable, unacceptable, unable to assess). Criteria rated as acceptable were assigned a score of 1 and then summed to determine a total quality score. Two investigators independently rated the scientific merit of each study, achieving a 95% agreement. The main discrepancy arose in assessing the degree of sample homogeneity. A consensus approach was used to resolve discrepancies and arrive at the final quality rating. Study quality was not used to exclude studies from the analysis; rather, studies were stratified post hoc to determine the effect of the quality rating on the correlation between the 2 methods. Methodological and substantive features of each study were coded and entered on a data collection form. Methodological features included the year of publication, type of study (ie, abstract or published study), quality rating, sample size, and number of data points. Substantive features included the type of study cohort, study setting, pulse oximeter model and probe location, co-oximeter and/or ABG analyzer model, the range and mean of arterial oxygen saturation levels, bivariate correlations and/or bias and preci-

§1,3,4,14,15,17,33,78,81,114,115

‖1,3,4,17,33,78,81,117,118

Table II
Research quality scoring form

Quality criteria	Acceptable	Unacceptable	Unable to assess
Predictor and criterion variables			
(1) Definition of predictor variable (model, probe type and location of sensor)	☐	☐	☐
(2) Definition of criterion measure (ABG analyzer, ABG source)	☐	☐	☐
(3) Reliability of criterion variable	☐	☐	☐
Methodological criteria			
(1) Predictor variable measured reliably (inter- and intra-rater reliably)	☐	☐	☐
(2) Criterion variable measured reliably (inter- and intra-rater reliably)	☐	☐	☐
(3) Measurements unbiased (concurrent and/or predictive)	☐	☐	☐
Sampling criteria			
(1) Sample size (data points)	☐	☐	☐
(2) Sample unbiased (homogeneity, confounding characteristics, stability)	☐	☐	☐
(3) Cross-validation studies	☐	☐	☐
Data analysis criteria			
(1) Validity estimates (method, technique, accounts for confounding factors)	☐	☐	☐
(2) Bias and precision estimates	☐	☐	☐
	☐	☐	☐

sion estimates between the pulse oximeter and co-oximeter values, as well as specific conditions or factors that affect pulse oximetry accuracy (skin pigmentation, hypoxia, temperature, perfusion, dyshemoglobinemia, hyperbilirubinemia).

Analysis. The Hunter and Schmidt[120] method was used to conduct the meta-analysis. First, a weighted mean correlation was calculated as the sum of all primary study correlations, divided by the sum of the sample size from each study. Next, the overall observed variance was calculated as the sample size–weighted sum of the squared deviation from this average correlation. Both these statistics were sample weighted such that studies based on larger samples were given more weight than studies based on smaller samples. Sample-weighting was based on the number of data points from repeated measurements. Second, a weighted-mean bias estimate was calculated as the sum of the weighted absolute mean bias values reported, divided by the sum of the primary study weights. The weight was calculated as the reciprocal of the variance components estimates. Finally, Hunter and Schmidt[120] recommend removing the variance caused by sampling error, because sampling error normally affects the variance across study coefficients, whereas other artifacts, such as measurement error and range restriction, affect the variance within the study coefficients. If sampling error accounts for more than 75% of the overall observed variance, then the correlation coefficients are thought to be constant across studies.[120] Therefore, the amount of variance among the study correlations remaining after removing the variance for sampling error was compared with the overall observed variance. Because the variance caused by sampling error failed to account for most of the overall observed variance, it was concluded that

correlations were not constant across studies, and a search for confounding variables was undertaken.

RESULTS

Characteristics of studies reviewed. Of the 247 articles retrieved, 150 studies examined the accuracy of pulse oximetry. Of these, 74 studies met the inclusion criteria. Studies were published from 1976 to 1994. Nine studies were published in the late 1970s, 43 studies were published in the 1980s, and 22 studies were published in the early 1990s. More than 86% of the studies were articles; 14% of the studies were abstracts. All abstracts that had no corresponding published article were retained for the analysis. The quality rating of the 74 studies ranged from 3 to 11, with a mean of 8.0 (SD = 1.75). Studies received a lower quality rating for several reasons. Studies reported the reliability of the predictor variable, but failed to report the reliability of the criterion variable. Forty-four studies reported the bivariate correlation between the predictor and the criterion variable, whereas 27 studies reported bias and precision estimates. In addition, studies rarely conducted cross-validation studies or included reliability estimates.

A summary of the studies[121-194] included in the meta-analysis is presented in Table III. Of the 74 studies, 24 studies tested 1 oximeter, and 50 studies tested from 2 to 20 different oximeter models. In the 74 studies, there were a total of 169 oximeter trials conducted on various combinations of oximeter models. There were 25 different oximeter manufacturers with a total of 41 different models (Table IV). More than 69% of the oximeter trials tested finger probes, 23.7% tested ear probes, 4.1% tested multiple probes, and the remainder (0.6%) tested forehead probes.

A repeated-measures design was most frequently used in the studies. Consequently, authors reported both the sample size and the number of data points (paired samples) measured. Studies that examined more than 1 oximeter often used different numbers of subjects and data points for each oximeter tested (Table III). In the 169 oximeter trials from the 74 studies, sample size ranged from 5 to 183 subjects, with a mean of 29.43 (SD = 32.37) and a mode of 8.00, and data points ranged from 13 to 524, with a mean of 110.66 (SD = 01.03) and a mode of 40.00. Although a variety of subjects were used, most were healthy adult volunteers (25.7%). There were also a variety of hospital in-patients such as respiratory patients (20.3%), thoracic surgical patients (5.4%), cardiac surgical patients (13.5%), critically ill patients (16.2%), and patients with more than 1 medical condition (10.8%). The remaining studies involved individuals with sleep disorders (1.4%) and athletes (5.4%). Studies were conducted in a variety of settings: laboratories (44.6%), intensive care units (27.0%), various hospital inpatient units (17.6%), and operating rooms (10.8%).

Most studies monitored or controlled the level of oxygenation in their subjects. Fifty-nine of the 74 studies reported subjects' lowest level of oxygenation, ranging from 36% to 96% (M = 70.29%, SD = 15.59). Fifty-seven studies reported subjects' highest level of oxygenation, ranging from 70% to 100% (M = 98.53%, SD = 4.29). There was a mean Sao_2 of 90.05% in the 20 studies that reported this value. Sao_2 standards were the Instrumentation Laboratory IL182 (1.4%), IL282 (37.8%), or IL482 (4.1%) co-oximeters; Corning C-2500 (6.8%) co-oximeter; Radiometer OSM-1 (1.4%), OSM-2 (13.5%), OSM-3 (9.5%) co-oximeters; and the American Optical Unistat (2.7%) co-oximeter; the remainder did not specify the model (5.4%). In 47.3% of the 74 studies, an ABG analyzer was used to measure Sao_2 or in conjunction with a co-oximeter. ABG analyzers consisted of the Radiometer ABL2 (5.4%), ABL3 (2.7%), ABL4 (1.4%), ABL300 (1.4%), BMS3 (1.4%), BMS-MK2 (1.4%) analyzers; Instrumentation Laboratory IL113 (4.1%), IL313 (2.7%), IL813 (2.7%), IL1312 (2.7%) analyzers; Ciba Corning 168 (1.4%), C-175 (5.4%), C-178 (5.4%), C-278 (1.4%) analyzers, or was not specified (8.1%).

Meta-analyses of pulse oximetry accuracy. Not all of the 74 studies included in the meta-analysis provided data on the number of subjects and data points (paired samples), as well as the correlation coefficient (r) and bias and precision estimates (Table V). The unweighted mean r, based on the 39 studies (62 oximeter trials) for which the r statistic and the number of data points were available, was 0.910 (var [r] = 0.011); the weighted mean r was 0.895 (var [r] = 0.014). A ranking of the 21 pulse oximeters used in these studies by correlation with Sao_2 is presented in Table VI. Based on 23 studies (82 oximeter trials) for which bias and precision estimates and the number of data points were available, the absolute mean bias was 1.99% ± 0.23.

In addition, the mean correlation was estimated based on the rating of study quality. Studies having a quality rating ≥ 9 out of 12 (22 studies, 43 oximeter trials) had an unweighted mean r of 0.908 (var [r] = 0.011) and a weighted mean r of 0.883 (var [r] = 0.016). To assess whether the recency of studies influenced the accuracy of pulse oximetry, studies were grouped according to the decade of publication. The unweighted and weighted mean

Table III
Summary of studies examining pulse oximetry accuracy

Year/author	Quality	Oximeter model	Probe location	Co-oximeter	Study population	Data sets (subjects)	*r*	Bias ± precision	
1976									
Flick and Block[121]	4	HP47201A	Ear	Not stated	Varied	123 (–)	0.988	–	–
Saunders et al[122]	8	HP47201A	Ear	RAD OSM-1	Healthy	223 (24)	0.970	–	–
1977									
Flick and Block[123]	7	HP47201A	Ear	IL 113	Respiratory	153 (10)	0.990	0.17	–
Flick and Block[124]	7	HP47201A	Ear	IL 113	Respiratory	133 (19)	0.988	–	–
Poppius and Viljanen[125]	7	HP47201A	Ear	Not stated	Respiratory	48 (45)	0.907	–	–
Scoggin et al[126]	7	HP47201A	Ear	AO Unistat	Respiratory	41 (36)	–	–	–
1978									
Chaudhary and Burki[127]	11	HP47201A	Ear	IL 113	Respiratory	57 (41)	0.900	–	–
Ishikawa et al[128]	4	HP47201A	Ear	IL 113	Respiratory	13 (13)	–	–	1.17
1979									
Douglas et al[129]	9	HP47201A	Ear	IL 182	Varied	465 (–)	0.940	–	–
1980									
Sarnquist et al[130]	7	Minolta 101	Finger	RAD OSM-2	Healthy	– (5)	0.973	–	–
Yoshiya et al[131]	8	Oximet 1471	Finger	RAD BMS-2	Critical/ICU	53 (15)	0.983	–	5.00
1981									
Cable[132]	8	HP47201A	Finger	IL 813	Varied	101 (79)	–	–1.37	–
1982									
Knill et al[133]	10	HP47201A	Ear	RAD BMS-3	Anesthetized	94 (34)	0.950	–	–
1983									
Fahey et al[134]	6	OH BIOX IIA	Ear	AO Unistat	Critical/ICU	90 (35)	0.880	–	–
Petterson et al[135]	8	OH BIOX IIA	Ear	IL 282	Critical/ICU	187 (79)	0.913	–	–
Yelderman and New[136]	8	NE N-100	Finger	IL 282	Healthy	79 (5)	0.980	–	–
1984									
Kim et al[137]	7	Minolta S-32	Finger	Not stated	Critical/ICU	21 (21)	0.716	–	–
Shippy et al[138]	10	OH BIOX II	Ear	IL 282	Respiratory	183 (183)	0.829	–	–
Shulman et al[139]	5	Not stated	Finger	IL 282	Thoracic surgery	– (11)	–	–	–

(Cont'd page 394)

Table III *(Cont'd)*
Summary of studies examining pulse oximetry accuracy

Year/author	Quality	Oximeter model	Probe location	Co-oximeter	Study population	Data sets (subjects)	*r*	Bias ± precision	
1985									
Brodsky et al[140]	7	NE N-100	Finger	IL 282	Thoracic surgery	35 (5)	0.930	–	–
Cecil et al[141]	9	OH BIOX IIA	Ear	IL 282	Critical/ICU	173 (79)	0.913	0.34	–
Mackenzie[142]	7	Not stated	Finger	IL 282	Healthy	139 (11)	0.980	–	–
		Not stated	Ear	IL 282	Healthy	138 (11)	0.970	–	–
Mihm and Halperin[143]	8	NE —	Finger	IL 282	Respiratory	131 (18)	0.960	–	–
Ries et al[144]	10	HP 47201A	Ear	IL 282	Respiratory	492 (105)	0.870	–0.70	–
		OH BIOX IIA	Ear	IL 282	Respiratory	194 (36)	0.770	–0.50	–
Tremper et al[145]	9	OH BIOX III	Finger	IL 282	Critical/ICU	326 (53)	0.570	1.40	3.10
Tweeddale and Douglas[146]	8	OH BIOX IIA	Ear	IL 282	Varied	322 (165)	–	1.50	3.00
1986									
Chapman et al[147]	8	OH BIOX II	Not stated	IL 282	Healthy	117 (8)	0.990	0.30	1.40
Smyth et al[148]	7	HP 47201A	Ear	Corning 175	Healthy	– (6)	0.850	–	–
Tytler et al[149]		OH BIOX II	Ear	AO Unistat	Healthy	– (6)	0.520	–	–
	8	NE N-101	Finger	RAD OSM-2	Healthy	72 (72)	–	0.40	1.20
1987									
Hansen and Casaburi[150]	6	OH BIOX IIA	Ear	IL 282	Varied	28 (14)	–	0.10	–
Hess et al[151]	9	PC Lifestat 1600	Finger	IL 282	Healthy	114 (9)	0.970	0.30	1.50
Kagle et al[152]	9	OH 3700	Multiple	C 2500	Healthy	40 (8)	0.980	–	–
		NE N-100	Finger	Not stated	Healthy	48 (8)	0.990	–	–
Severinghaus and Naifeh[153]	9	NE N-100	Ear	RAD OSM-3	Healthy	60 (–)	–	–0.40	11.70
		OH 3700	Ear	RAD OSM-3	Healthy	60 (–)	–	2.40	8.80
		NO 500	Finger	RAD OSM-3	Healthy	120 (–)	–	1.10	5.40
		CR 502	Ear	RAD OSM-3	Healthy	36 (–)	–	–	3.40
		CR 501+	Ear	RAD OSM-3	Healthy	55 (–)	–	12.00	13.30
		PC Lifestat 1600	Ear	RAD OSM-3	Healthy	54 (–)	–	2.00	4.30
		MI Pulsox 7	Finger	RAD OSM-3	Healthy	36 (–)	–	–4.30	5.20
Viitanen et al[154]	8	NE N-100	Finger	IL 282	Thoracic surgery	90 (10)	0.930	–2.90	–
Warley et al[155]	8	OH 3700	Multiple	RAD ABL-2	Varied	65 (10)	–	–	–

1988										
Cecil et al[156]	9	NE N-100	Finger	IL 282	Varied	329	(152)	0.830	–	–
		OH 3700	Finger	IL 282	Varied	329	(152)	0.560	–	–
Gabrielczyk and Buist[157]	10	NE N-100	Finger	RAD OSM-z	Cardiac surgery	68	(21)	0.730	0.60	1.60
Jones et al[158]	9	OH 3700	Finger	IL 282	Respiratory	–	(40)	0.950	1.86	3.11
Kurki et al[159]	8	NE N-100	Finger	IL 282	Cardiac surgery	–	(5)	0.928	–	–
		OH BIOX III	Finger	IL 282	Cardiac surgery	–	(15)	0.924	–	–
Mendelson et al[160]	9	DA Accusat	Forehead	IL 282	Healthy	110	(10)	0.980	1.38	1.85
Mendelson et al[161]	10	DA Accusat	Finger	IL 282	Healthy	135	(15)	0.990	–	–
		HP 47201A	Ear	IL 282	Healthy	135	(15)	0.990	–	–
Nickerson et al[162]	10	OH 3700	Ear	IL 282	Healthy	165	(5)	–	–2.60	2.10
		CR 501+	Finger	IL 282	Healthy	165	(5)	–	–1.00	2.80
		NE N-100	Finger	IL 282	Healthy	165	(5)	–	–4.00	1.70
		NO 500	Finger	IL 282	Healthy	165	(5)	–	–0.10	1.60
Niehoff et al[163]	8	OH BIOX III	Multiple	Corning 178	Critical/ICU	138	(23)	0.640	–	–
Tashiro et al[164]	9	OH 3700	Finger	Corning 2500	Healthy	54	(6)	0.980	–	–
Taylor and Whitwam[165]	8	Bird 4400	Finger	IL 282	Critical/ICU	–	(20)	0.981	–2.34	–
		CR 501+	Finger	IL 282	Critical/ICU	–	(20)	0.966	–2.00	–
		NO 500	Finger	IL 282	Critical/ICU	–	(20)	0.878	–2.80	–
		OH 3700	Finger	IL 282	Critical/ICU	–	(20)	0.976	–2.40	–
		NE N-100	Finger	IL 282	Critical/ICU	–	(20)	0.979	–2.00	–
1989										
Choe et al[166]	10	OH 3700	Finger	RAD OSM-3	Healthy	62	(8)	0.977	–2.80	2.20
		MI Pulsox 7	Finger	RAD OSM-3	Healthy	62	(8)	0.979	–0.10	2.00
		NO 500	Finger	RAD OSM-3	Healthy	62	(8)	0.981	–0.40	1.90
		PC Lifestat 1600	Finger	RAD OSM-3	Healthy	62	(8)	0.975	–0.60	2.20
		Datex Satlite	Finger	RAD OSM-3	Healthy	62	(8)	0.982	–0.80	2.10
		RAD Oxi 100	Finger	RAD OSM-3	Healthy	62	(8)	0.981	–2.50	2.00
Decker et al[167]	10	CR 501+	Finger	IL 282	Sleep disorder	48	(16)	–	–1.12	5.50
Palve and Vuori[168]	10	OH 3700	Finger	RAD OSM-2	Cardiac surgery	66	(15)	–	2.20	1.10
		NE N-100	Finger	RAD OSM-2	Cardiac surgery	–	(11)	–	3.90	1.40
Powers et al[169]	10	OH 3700	Multiple	IL 282	Healthy	114	(10)	0.910	–	–
		OH BIOX IIA	Ear	IL 282	Healthy	114	(10)	0.820	–	–

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Table III (*Cont'd*)
Summary of studies examining pulse oximetry accuracy

Year/author	Quality	Oximeter model	Probe location	Co-oximeter	Study population	Data sets (subjects)		r	Bias ± precision	
Ries et al[170]	7	OH BIOX III	Ear	Not stated	Respiratory	476	(136)	–	1.40	–
		HP 47201A	Ear	Not stated	Respiratory	524	(154)	–	–0.60	–
1989										
Severinghaus et al[171]	10	Biochem 3040	Finger	RAD OSM-3	Healthy	239	(10)	0.975	–	–
		CR 501+	Finger	RAD OSM-3	Healthy	120	(10)	0.959	–	–
		Datex Satlite	Finger	RAD OSM-3	Healthy	120	(10)	0.933	–	–
		Kontron 7840	Finger	RAD OSM-3	Healthy	115	(10)	0.966	–	–
		MI Pulsox 7	Finger	RAD OSM-3	Healthy	123	(10)	0.912	–	–
		NE N-200	Finger	RAD OSM-3	Healthy	117	(10)	0.947	–	–
		OH 3700	Finger	RAD OSM-3	Healthy	120	(10)	0.952	–	–
			Ear	RAD OSM-3	Healthy	120	(10)	0.985	–	–
			Finger	RAD OSM-3	Healthy	240	(10)	0.977	–	–
			Finger	RAD OSM-3	Healthy	120	(10)	0.942	–	–
			Finger	RAD OSM-3	Healthy	250	(10)	0.961	–	–
			Finger	RAD OSM-3	Healthy	–	(10)	–	–	–
			Finger	RAD OSM-3	Healthy	–	(10)	–	–	–
			Finger	RAD OSM-3	Healthy	–	(10)	–	–	–
Veyckemans et al[172]	9	NE N-100	Finger	Corning 2500	Healthy	49	(46)	–	1.70	2.70
1990										
Barthelemy et al[173]	9	Datex Satlite	Finger	RAD OSM-3	Respiratory	107	(57)	–	–0.61	1.76
		Kontron 7840	Finger	RAD OSM-3	Respiratory	71	(57)	–	–0.33	3.97
			Finger	RAD OSM-3	Respiratory	83	(57)	–	–1.54	1.87
			Finger	RAD OSM-3	Respiratory	153	(57)	–	0.11	3.16
			Finger	RAD OSM-3	Respiratory	106	(57)	–	0.89	3.55
			Finger	RAD OSM-3	Respiratory	151	(57)	–	–2.26	3.25
			Finger	RAD OSM-3	Respiratory	70	(57)	–	0.15	1.78
			Finger	RAD OSM-3	Respiratory	33	(57)	–	–3.26	6.28
Brown et al[174]	3	OH BIOX IIA	Ear	Not stated	Athletes	–	(8)	–	–0.20	–
Desiderio et al[175]	7	NE N-100	Finger	Corning 2500	Thoracic surgery	19	(19)	–	2.81	1.88
		NO 500	Finger	Corning 2500	Thoracic surgery	19	(19)	–	1.21	1.66
Escourrou et al[176]	9	OH 3700	Ear	RAD OSM-2	Respiratory	94	(48)	0.800	–	–
		NE N-200	Finger	RAD OSM-2	Respiratory	47	(24)	0.800	–	–
		CR 501+	Ear	RAD OSM-2	Respiratory	58	(29)	0.940	–	–

Peters et al[177]	4	Not stated	Not stated	Not stated	Cardiac surgery	219	(51)	0.958	–	–
Warren et al[178]	6	CR 504	Not stated	Corning 2500	Athletes	0	(12)	–	–0.84	0.72
1991								–		
Chelluri et al[179]	9	NE N-10	Finger	RAD OSM-3	Critical/ICU	18	(18)	–	–0.05	1.87
Clayton et al[180]	8	Biochem 3040	Finger	IL 482	Cardiac surgery	40	(40)	–	0.01	2.95
		Datex Satlite	Finger	IL 482	Cardiac surgery	40	(40)	–	0.19	1.75
		Invivo 4500	Finger	IL 482	Cardiac surgery	40	(40)	–	0.20	2.05
		Simed S-100	Finger	IL 482	Cardiac surgery	40	(40)	–	–0.40	2.20
		SM Oxyshuttle	Finger	IL 482	Cardiac surgery	40	(40)	–	0.73	2.25
		DA Accusat	Finger	IL 482	Cardiac surgery	40	(40)	–	0.81	2.18
		Nonin 8640D	Finger	IL 482	Cardiac surgery	40	(40)	–	0.83	2.35
		CR 503	Finger	IL 482	Cardiac surgery	40	(40)	–	0.83	1.30
		CR 504	Finger	IL 482	Cardiac surgery	40	(40)	–	0.87	2.40
		MI Pulsox 7	Finger	IL 482	Cardiac surgery	40	(40)	–	1.00	2.38
		SPEC Pulsat	Finger	IL 482	Cardiac surgery	40	(40)	–	–1.07	3.75
		PC Lifestat 1600	Finger	IL 482	Cardiac surgery	40	(40)	–	1.13	1.90
		RAD Oxi 100	Finger	IL 482	Cardiac surgery	40	(40)	–	–1.13	2.50
		OH 3700	Finger	IL 482	Cardiac surgery	40	(40)	–	1.27	2.90
		OH 3740	Finger	IL 482	Cardiac surgery	40	(40)	–	1.33	2.65
		Pulsemate BX-5	Finger	IL 482	Cardiac surgery	40	(40)	–	1.47	1.85
		NO 505	Finger	IL 482	Cardiac surgery	40	(40)	–	1.67	1.35
		NE N-200	Finger	IL 482	Cardiac surgery	40	(40)	–	2.20	1.10
		Kontron 7840	Finger	IL 482	Cardiac surgery	40	(40)	–	2.63	0.96
		Engstrom EOS	Finger	IL 482	Cardiac surgery	40	(40)	–	–4.50	5.78
Hannhart et al[181]	8	Engstrom EOS	Finger	RAD OSM-2	Healthy	–	(8)	–	0.10	1.40
		NO 505	Finger	RAD OSM-2	Healthy	–	(8)	–	–0.20	1.50
		SPEC Pulsat	Finger	RAD OSM-2	Healthy	–	(8)	–	0.40	1.90
		OH 3740	Finger	RAD OSM-2	Healthy	–	(8)	–	0.70	1.30
		Biochem 3040	Finger	RAD OSM-2	Healthy	–	(8)	–	0.80	2.50
		NE N-200	Finger	RAD OSM-2	Healthy	–	(8)	–	0.90	1.60
		OH 3700	Finger	RAD OSM-2	Healthy	–	(8)	–	0.90	1.90
		Invivo 4500	Finger	RAD OSM-2	Healthy	–	(8)	–	0.90	2.20
		CR 502	Finger	RAD OSM-2	Healthy	–	(8)	–	1.20	2.10
		RAD Oxi 100	Finger	RAD OSM-2	Healthy	–	(8)	–	–1.50	2.10
		Datex Satlite	Finger	RAD OSM-2	Healthy	–	(8)	–	1.60	2.60
		PC Lifestat 1600	Finger	RAD OSM-2	Healthy	–	(8)	–	1.70	2.30
		Kontron 7840	Finger	RAD OSM-2	Healthy	–	(8)	–	2.30	2.20
		CTK Oxyshuttle	Finger	RAD OSM-2	Healthy	–	(8)	–	3.10	3.00

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Table III *(Cont'd)*
Summary of studies examining pulse oximetry accuracy

Year/author	Quality	Oximeter model	Probe location	Co-oximeter	Study population	Data sets (subjects)	r	Bias ± precision	
Hannhart et al[182]	8	NE N-101	Finger	RAD OSM-2	Respiratory	51 (17)	–	3.60	3.50
		OH BIOX III	Finger	RAD OSM-2	Respiratory	51 (17)	–	3.10	3.90
		NE N-200	Finger	RAD OSM-2	Respiratory	51 (17)	–	0.40	2.20
		CTK Oxyshuttle	Finger	RAD OSM-2	Respiratory	51 (17)	–	1.20	3.00
		RAD Oxi 100	Finger	RAD OSM-2	Respiratory	51 (17)	–	0.80	2.50
		OH 3700	Finger	RAD OSM-2	Respiratory	51 (17)	–	0.80	2.50
Ibanez et al[183]	10	OH 3700	Finger	IL 282	Critical/ICU	24 (24)	0.820	–2.49	4.24
Modica and Rizzo[184]	7	MI Pulsox 7	Finger	IL 482	Respiratory	– (123)	–	–	–
Palve and Vuori[185]	9	OH 3700	Ear	RAD OSM-2	Cardiac surgery	– (33)	–	2.00	1.90
		NE N-100	Finger	RAD OSM-2	Cardiac surgery	– (33)	–	2.50	5.00
		Datex Satlite	Finger	RAD OSM-2	Cardiac surgery	– (33)	–	1.60	1.10
Palve and Vuori[186]	9	OH 3700	Ear	RAD OSM-2	Cardiac surgery	– (18)	–	–1.60	1.30
		NE N-200	Finger	RAD OSM-2	Cardiac surgery	– (12)	–	2.20	1.70
		Datex Satlite	Finger	RAD OSM-2	Cardiac surgery	– (17)	–	–2.00	1.70
Stewart and Rowbottom[187]	6	OH 3700	Multiple	RAD OSM-2	Cardiac surgery	– (42)	–	–	–
Withington et al[188]	7	OH 3700	Finger	IL 1312	Cardiac surgery	312 (20)	–	–	–
1992									
Martin et al[189]	11	OH 3740	Multiple	IL 282	Athletes	273 (11)	0.957	–	–
Menglekoch et al[190]	6	OH 3740	Finger	IL 282	Healthy	67 (10)	0.680	1.26	1.47
Norton et al[191]	11	OH 3700	Ear	RAD OSM-3	Athletes	40 (10)	0.889	–	–
Palve[192]	8	CR 504	Ear	RAD OSM-3	Cardiac surgery	– (23)	–	–0.40	1.50
1993									
Wong et al[193]	4	Several	Multiple	IL 282	Critical/ICU	238 (55)	–	0.17	2.22
1994									
Thrush and Hodges[194]	9	CTK 8700	Finger	IL 482	Healthy	– (22)	–	1.00	1.00
		CTK Oxyshuttle	Finger	IL 482	Healthy	– (22)	–	1.00	1.00
		OH 3700	Finger	IL 482	Healthy	– (22)	–	1.00	1.00
		CAT MiniOx IV	Finger	IL 482	Healthy	– (22)	–	–	1.00

ICU, Intensive care unit; *CAT,* Catalyst; *CR,* Criticare; *CTK,* Critikon; *DA,* Datascope; *HP,* Hewlett Packard; *KON,* Kontron; *MI,* Minolta; *NE,* Nellcor; *NO,* Novametrix; *OH,* Ohmeda; *PC,* Physio-Control; *RAD,* Radiometer; *SM,* SensorMedics; *SPEC,* Spectromed.

correlation statistic for studies published in the 1970s (7 studies, 7 oximeter trials) was 0.955 (var [r] = 0.002) and 0.959 (var [r] = 0.005), respectively; in the 1980s (26 studies, 47 oximeter trials) was 0.913 (var [r] = 0.012) and 0.882 (var [r] = 0.0170), respectively; and in the 1990s (6 studies, 8 oximeter trials) was 0.855 (var [r] = 0.010) and 0.899 (var [r] = 0.008), respectively. Correlations of pulse oximetry with Sao_2 were estimated by type of subject (Table VII). The highest correlation was in healthy adult volunteers (r = 0.957), with the lowest in critically ill patients (r = 0.760).

Four studies (6 oximeter trials) compared pulse oximetry accuracy with ear and finger probes. Of these, only 3 studies (3 oximeter trials) provided the data points and the correlational statistic (Table VIII). For oximeters using the ear probe, the unweighted and weighted mean r was 0.938 (var [r] = 0.002) and 0.934 (var [r] = 0.001), respectively. For oximeters using the finger probe, the unweighted and weighted mean r was 0.963 (var [r] = 0.001) and 0.967 (var [r] = 0.001), respectively. Finger probes were found to have a statistically significant higher correlation with Sao_2 than ear probes ($Z = 5.21$, $P < .0001$).

Meta-analysis of factors affecting pulse oximetry accuracy. Many factors affect the accuracy of pulse oximetry. Only 6 of those factors, however, were examined in a sufficient number of oximeter trials to warrant subanalyses (Table IX).

Hypoxia. Fifteen studies (61 oximeter trials), conducted between 1985 and 1991, tested the accuracy of pulse oximetry during hypoxic conditions. Of these, only 5 studies (15 oximeter trials) provided both the correlation statistic and the number of data points. An unweighted and weighted mean r of 0.924 (var [r] = 0.008) and 0.938 (var [r] = 0.006), respectively, were found during hypoxic conditions (range, 67.6% to 87.8% Sao_2). Subjects were hypoxic due to surgery, deteriorating health, or induced by rebreathing CO_2.

The Mihm and Halperin[143] regression analysis of 23 data sets from 3 patients, in whom arterial desaturation of less than 70% developed, demonstrated a correlation of 0.99 with use of the Nellcor (model not specified) pulse oximeter. Kagle et al[152] reported a correlation of 0.96 with use of an Ohmeda 3700 (ear probe) oximeter, but a correlation of 0.78 with use of an Ohmeda 3700 (finger probe) oximeter when the Sao_2 was below 90%. Brodsky et al[140] found the Nellcor N-100 was accurate in hypoxic ranges of 79% to 90% during 1-lung ventilation. Tremper et al,[145] in contrast, found a correlation of 0.65 for the Ohmeda BIOX III (finger probe) in hypoxic ranges of 80.9% to 95.0%. Severinghaus et al[171] studied the accuracy of pulse oximeters from 14 manufacturers during brief hypoxic episodes (45.0% to 90.0% Sao_2). Although the correlations were strong, the data showed substantial differences in bias and precision estimates between pulse oximeters at low saturation; the most common being an underestimation of saturation and failing precision.

Table IV
Manufacturers and models of pulse oximeters

Manufacturers	Models
Biochem	Microspan 3040, Ox2000
Bird	4400
Catalyst	MiniOx IV
Colin	Pulsemate BX-5
Criticare	504, 503, 502, 501+
Critikon	Oxyshuttle, Dinamap Plus 8700, Oxytrak
Datascope	Accusat
Datex	Satlite
Engstrom	EOS
Hewlett Packard	47201A
Invivo	4500
Kontron	7840
Minolta	Pulsox 7, S-32, 101
Nellcor	N-10, N-100, N-101, N-200
Nonin	8604D
Novametrix	500, 505
Ohmeda	BIOX II, IIA, III, 3700, 3740
Oximet	1471
Physio-Control	Lifestat 1600
PPG-Hellige	4500
Puritan	240
Radiometer	OXI
SensorMedics	Oxyshuttle
SiMed	S-100
Spectromed	Pulsat

Dyshemoglobinemia. Five studies (6 oximeter trials) examined the effects of dyshemoglobinemia on pulse oximetry accuracy. The number of data points examined ranged from 33 to 326 (M = 103, SD = 114.88). The unweighted mean r was 0.817 (var [r] = 0.028); the weighted mean r was 0.717 (var [r] = 0.717). Carboxyhemoglobin levels ranged from 5.87% to 9.10%. The Douglas et al[129] results indicated that the HP 47201A ear oximeter can measure

Table V
No. of studies/No. of oximeter trials

	Reported No. of subjects	Reported No. data points
Reported correlation	42 Studies/71 oximeter trials	39 Studies/62 oximeter trials
Reported bias and precision	29 Studies/103 oximeter trials	23 Studies/82 oximeter trials
Reported correlation, bias and precision	9 Studies/14 oximeter trials	9 Studies/27 oximeter trials

Table VI
Ranking of 21 pulse oximeters by correlation with oxygen saturation

Oximeter model	Type of probe	No. oximeter trials	Total No. subjects	Total No. data points	*r*
Datascope Accusat	Finger/flex	2	25	245	0.986
Oximet 1471	Finger	1	15	53	0.983
Novametrix 500	Finger	1	8	62	0.981
Physio-Control Lifestat 1600	Ear/finger	3	27	120	0.977
Puritan 240	Finger	1	10	240	0.977
Biochem Microspan 3040	Finger	1	10	239	0.975
Kontron 7840	Finger	1	10	115	0.966
SiMed S-100	Finger	1	10	250	0.961
Radiometer OXI	Finger	2	18	182	0.955
Criticare 501+	Ear/finger	2	39	178	0.953
Datex Satlite OS-103	Finger	2	18	182	0.950
Hewlett Packard 47201A	Ear	10	293	1923	0.938
Minolta Pulsox 7	Finger	2	18	185	0.934
Nellcor N-200	Finger	2	34	164	0.905
Ohmeda BIOX 3740	Finger/multiple	2	21	340	0.902
Ohmeda BIOX II	Ear	2	191	300	0.892
Nellcor N-100	Finger	6	201	649	0.869
Ohmeda BIOX IIA	Ear	5	239	758	0.858
Ohmeda BIOX 3700	Ear/finger	9	276	877	0.781
Minolta S-32	Finger	1	21	21	0.716
Ohmeda BIOX III	Finger/multiple	2	76	464	0.591

Sao_2 in the range of 65% to 100% with an accuracy of ± 4%, if the concentration of CoHb is less than 3%. The oximeter was found to be sensitive to CoHb, progressively overestimating arterial saturation as CoHb concentration increased from 0% to 18%. Similarly, Shippy et al[138] found that the Ohmeda BIOX II ear oximeter provided accurate, continuous measurement of patients' oxygenation status in the absence of elevated CoHb levels in the blood. When the CoHb level was more than 3% in 129 paired samples, the Ohmeda BIOX II ear oximeter progressively overestimated Sao_2. Tashiro et al[164] reported CoHb-induced errors in healthy volunteers with use of the Ohmeda BIOX 3700. When the percentage fraction of CoHb was increased, the Sao_2 was overestimated. Finally, Powers et al[169] evaluated the Ohmeda 3700 (finger and ear probes) and BIOX IIa (ear probe) pulse oximeters during cycle ergometer in healthy smoking and nonsmoking volunteers, and suggested that pulse oximetry is useful in estimating changes in Sao_2 during exercise in subjects with CoHb < 3%. Trem-

Table VII
Correlation of pulse oximetry with oxygen saturation by type of subject

Type of subject	No. of studies	Total No. of subjects	Total No. of data points	No. of oximeter trials	*r*
Healthy adult volunteers	13	318	3683	32	0.957
Anesthetized patients	1	34	94	1	0.950
Athletes	2	21	313	2	0.948
Thoracic surgical patients	2	15	125	2	0.930
Cardiac surgical patients	2	72	287	2	0.904
Respiratory patients	8	558	1590	11	0.880
Critically ill/ICU patients	8	329	1012	8	0.760

Table VIII
Probe location

Location	No. of studies	No. of oximeters	Mean unweighted *r* (Var *r*)	Mean weighted *r* (Var *r*)
Ear	3	3	0.938 (0.002)	0.934 (0.001)
Finger	3	3	0.963 (0.001)	0.967 (0.001)*

*$Z = 5.21$; $P < .0001$.

Table IX
Studies examining factors that affect pulse oximeter accuracy

Condition	No. of studies/ No. of oximeter trials	Mean unweighted *r* (Var *r*)	Mean weighted *r* (Var *r*)
Hypoxia	5 Studies/15 oximeter trials	0.924 (0.008)	0.938 (0.006)
Perfusion	3 Studies/3 oximeter trials	0.717 (0.049)	0.582 (0.004)
Dyshemoglobinemia	5 Studies/6 oximeter trials	0.817 (0.028)	0.717 (0.035)
Temperature	3 Studies/3 oximeter trials	0.760 (0.043)	0.665 (0.024)
Skin pigmentation	1 Study/2 oximeter trials	0.800 (0.0002)	0.800 (0.0002)
Hyperbilirubinemia	1 Study/1 oximeter trial	0.850	—

per et al[145] studied the effects of hemodynamics on the accuracy of the Ohmeda BIOX III (finger probe) in 326 paired samples from critically ill patients and concluded that conditions of extreme anemia may lead to a weakened pulse-absorbance signal.

Perfusion. Although 9 studies (33 oximeter trials) examined the effects of perfusion states on pulse oximetry, only 3 studies (3 oximeter trials) provided a correlation statistic. The number of data points examined were 9, 12, and 326, respectively. The unweighted and weighted mean *r* were 0.717

(var [r] = 0.049) and 0.582 (var [r] = 0.004), respectively. Fahey et al[134] reported that when the Ohmeda BIOX IIA pulse oximeter alarm sounded for systolic blood pressure < 100 mm Hg in 12 paired samples, the accuracy decreased. Tremper et al[145] suggested that at extremes of systemic resistance, the Ohmeda BIOX III oximeter may be unable to estimate Sao_2. In contrast, Mihm and Halperin[143] obtained reliable data with use of a Nellcor pulse oximeter (model not specified) in 9 out of 131 data sets in which the mean arterial pressure was < 60 mm Hg. Clayton et al[195] recommended the use of finger probes, rather than ear, nose, or forehead probes, for patients with poor peripheral perfusion.

Temperature. Of the 5 studies (7 oximeter trials) that examined the effect of temperature on pulse oximetry accuracy, only 3 studies (3 oximeter trials) provided the correlation statistic. The mean temperature range in these studies was 28.6°C to 34.8°C. The unweighted mean *r* was 0.760 (var [r] = 0.043), whereas the weighted mean *r* was 0.665 (var [r] = 0.024). Under conditions of hypothermia (T < 35°C), Tremper et al[145] found that the Ohmeda BIOX III (finger probe) oximeter had difficulty processing a reliable signal. Gabrielczyk and Buist[157] evaluated the accuracy of the Nellcor N-100 (finger probe) in hypothermic patients (core temperature ≤ 35°C) after cardiac surgery and found that Sao_2 was overestimated compared with in vitro oximetry, with a mean bias of 0.6%. In contrast, Peters et al,[177] in 84 paired data sets, found high correlations regardless of whether the patient was hypothermic or normothermic. However, this study received a quality rating of 4 out of 12.

Skin pigmentation. Three studies (5 oximeter trials) assessed how the degree of skin pigmentation affected the accuracy of pulse oximetry. Of these studies, only 1 study (2 oximeter trials) provided both the correlation statistic (*r* = 0.790 and 0.810) and data points (N = 43). The mean unweighted and weighted *r* was 0.800 (var [r] = 0.0002). Cecil et al,[156] in a subset of their study population that was black (15 patients; 43 data points), demonstrated that both the Nellcor N-100 (finger probe) and the Ohmeda 3700 (finger probe) oximeters had different regression lines from those in the total data set, with the Nellcor N-100 demonstrating a statistically significant difference from the standard IL282 co-oximeter. They suggested that the greater inaccuracy demonstrated by both oximeters over the inaccuracy seen in their total sample most likely was due to the wide range of pigmentation levels in the patients tested.

Hyperbilirubinemia. Hyperbilirubinemia was investigated in 3 studies (3 oximeter trials); however, only 1 study provided the correlation statistic (*r* = 0.850). Chaudhary and Burki[127] compared oxygen saturation measurements, with use of the Hewlett Packard 47201A (ear probe) oximeter, with that derived from Sao_2 saturation measurements in 11 patients with jaundice who had serum bilirubin concentrations between 2.7 and 35 mg/100 mL. The correlation was 0.85; however, the Sao_2 values were significantly underestimated.

DISCUSSION

For the 21 oximeter models included in the meta-analysis, the correlation coefficient (*r*) ranged from 0.986 to 0.591, with variability found even within the same model. Because pulse oximeters are calibrated empirically with use of observations taken from healthy volunteers, most models were found to be accurate within 2% (± 1 SD) or 5% (± 2 SD) of in vitro oximetry in the range of 70% to 100% Sao_2 saturation.[12,196] Of the 23 studies (82 oximeter trials) for which bias and precision estimates were available, 42.68% underestimated Sao_2, with a range of bias (precision) from −13.20% (8.03) to 12.00% (13.30). Spo_2 estimates below 70% oxygen saturation were relatively inaccurate. Readings from finger probes were more accurate than ear probes. This may be due to such factors as circulation time, probe specifications, and variations in cutaneous vasculature.

Pulse oximeters do have accuracy limitations, which clinicians must clearly understand to ensure that they are used most effectively. Pulse oximeters may fail to record accurately the true Sao_2 during severe or rapid desaturation, during physiological extremes such as hypotension and hypothermia, during other unstable hemodynamic states, or with dyshemoglobinemia, vital dyes, low perfusion states, and motion. The most important criterion for pulse oximeters is that they effectively warn of dangerous levels of oxygen saturation and changes in pulse rate.

As expected, those studies involving healthy adult volunteers had the strongest aggregate mean correlation coefficient (*r* = 0.957); whereas estimates obtained from respiratory and critically ill patients were weakest at 0.880 and 0.760, respectively. Pulse oximetry has become an established monitoring technique for patients during anesthesia in the operating room, and it plays an important role in monitoring patients in the emergency department.[197] Investigations have addressed the impact of routine clinical monitoring of oxygen sat-

uration in the critically ill population, and important contributions have been made to the care of patients with compromised respiratory or hemodynamic conditions. Because critically ill patients are a heterogeneous cohort, it is difficult to isolate all parameters affecting the accuracy of pulse oximetry when used in critical care.[27,198-200] Studies of pulse oximetry use in operating and recovery rooms have enough similarities with critical care that findings have been inferred to patient outcomes in critically ill patients. Further study is needed to determine the impact on pulse oximetry accuracy of such conditions as circulatory compromise from hypotension and vasoactive drugs.

In reviewing the studies for this meta-analysis, several issues arose. When the new method (pulse oximetry) was compared with the gold standard (in vitro saturation measurements from arterial blood samples), the degree of error of the new method was determined. Yet, both methods have a degree of uncertainty. First, there was considerable variation in the co-oximeters used in the primary studies included in the meta-analysis. There were 3 manufacturers (Radiometer, Ciba Corning, Instrumentation Laboratory) of 14 models of ABG analyzers, and 4 manufacturers (Instrumentation Laboratory, Ciba Corning, Radiometer, American Optical) of 7 models of co-oximeters. Second, co-oximeters also have a degree of error. They are reported to be accurate within ± 1.0% oxyhemoglobin (O_2Hb) in the Sao_2 range of 80% to 100%,[26,29] but with a relatively high reported coefficient of variation (CV of 5.1% ± 3.2%).[16] Also, the validity of the criterion measure used often was not reported. This variation in the standard used for comparison of pulse oximetry introduced a potential source of error in determining the overall aggregate mean estimate.

There are both technologic and physiological limitations to the accuracy of pulse oximetry. The accuracy of the Spo_2 estimate is dependent on the empirical calibration curve programmed into the device, which is, in turn, only as accurate as the in vitro laboratory co-oximeter standard used to generate it.[26,119] Also, an instrument error resides in the technology of pulse oximeters. The bias produced with pulse oximetry is related to the acquisition and processing of the data. Other sources of variation in the data are due to either between-subject variation or within-subject variation. Between-subject variation depends on several factors, such as position of the probe, local circulation, CoHb and bilirubin levels, or intravenous dyes; whereas within-subject variation relates to transient conditions such as hemodynamic instability. Because error is assumed constant in 1 subject with 1 oximeter, the degree of error is more accurately evaluated using continuous measures rather than absolute values.

Further sources of variation were identified in the primary studies. First, some studies were conducted with healthy volunteers; whereas others were carried out with patients in a variety of clinical settings under perhaps less than optimal conditions. Second, because pulse oximeters are empirically calibrated, the algorithm programmed into each oximeter undergoes a series of revisions. Earlier models versus later models would therefore tend to show less agreement between measures. However, the software revision used in the primary studies was not always specified. Third, missing data were a problem. Even though repeated paired samples were used in the primary studies, often either the sample size or number of data points (paired samples) were not reported.

When comparing methods, the data analyses in the primary studies usually involved a correlation coefficient (r), with a significance value (P), and a linear regression slope and intercept. The correlation coefficient is a measure of association, but not a measure of agreement. To determine the degree of confidence in pulse oximetry, Bland and Altman[83] recommended calculating the bias and precision between the 2 measures. Because many investigators only provided correlation coefficients or linear regression analyses, it was difficult to compare results in terms of accuracy without bias and precision estimates. There were no studies found that aggregated bias and precision estimates.

CONCLUSION

Continuous monitoring of arterial oxygen saturation with use of pulse oximetry is used in a variety of settings with a variety of patients to provide early detection of a decrease in oxygen saturation. However, several factors have been found to affect the accuracy of pulse oximetry. Pulse oximetry uses a photoplethysmographic signal to determine oxygen saturation, which is affected by pulse variations, as well as a variety of other physiological parameters.[4,201-204] Dark skin pigmentation, as well as high levels of CoHb, may cause overestimation of oxygen saturation. Measures of heart rate with use of pulse oximeters may be limited in the higher ranges, attributing to an underestimation of oxygen saturation in heavy exercise. Conditions of low perfusion or unstable hemodynamic states also affect the accuracy of oxygen saturation estimates. Although probe location is an

issue, more recent results favor finger probes rather than ear probes.

The primary advantage of pulse oximeters is that they provide a continuous and noninvasive measurement of arterial oxygen saturation. This provides an opportunity for deviations from patients' baseline to be noticed, an early warning signal to clinicians to prevent the consequences of desaturation, and an end-point to guide therapeutic interventions. It is important to realize, however, that pulse oximetry does not present a complete picture of oxygen transport. Information is not provided about hemoglobin concentration, cardiac output, efficiency of oxygen delivery to the tissues, the consumption or sufficiency of oxygenation, or adequacy of ventilation.[205-207] Carbon dioxide tension and acid-base balance can only be obtained by ABG analysis. Pulse oximetry is a valuable, noninvasive technology when combined with an understanding of its uses and limitations.

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