Anaesthesia, 1991, Volume 46, pages 3–10

A comparison of the performance of 20 pulse oximeters under conditions of poor perfusion

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Summary

The performance of 20 pulse oximeters with finger probes was evaluated by comparison of their readings with directly measured arterial blood oxygen saturations. The samples were taken from patients who had undergone cardiac surgery under hypothermic cardiopulmonary bypass and had poor peripheral perfusion. The mean difference (bias, accuracy), standard deviation (precision) and drop-out rate for each pulse oximeter was determined. An overall ranking of performance of each pulse oximeter was calculated using five criteria (accuracy, precision, number of readings within 3% of standard, percentage of readings given within 3% of standard, expected overread limit in 95% of cases). Two pulse oximeters achieved a combination of accuracy and precision such that 95% of measurements would be expected to be within 4% of the co-oximeter value; these two also had the lowest drop-out rate.

Key words

Equipment: pulse oximetry.
Measurement.

Pulse oximeters are widely used during anaesthesia in the peri-operative period, and in critically ill patients. Pulse oximetry has developed rapidly over the last 5 years: its history, basic principles, applications and limitations have been the subject of three recent comprehensive reviews.[1–3] The technique has come into wide clinical use so it is important to examine circumstances wherein its reliability may be questioned. Performance under conditions of poor perfusion is one such circumstance.

Pulse oximeters require adequate plethysmographic pulsations to allow them to distinguish arterial blood light absorption from background venous blood and tissue light absorption. Only 1–5% of the total signal is processed to calculate the haemoglobin saturation.[4] Hypothermia, vasoconstriction and low cardiac output may impair peripheral perfusion, and thus plethysmographic pulsation and the portion of total signal used to detect haemoglobin saturation.

Other attempts have been made to study the performance of pulse oximeters under conditions of poor peripheral perfusion. Morris produced venous congestion using a pneumatic tourniquet and took this to represent poor peripheral perfusion.[5] Fifteen oximeters were compared under these conditions, but the validity of this technique was questioned.[6] Superficial cooling was also used to reduce peripheral perfusion.[7] However, in both these studies observations were not compared with the standard reference of co-oximetry.

This study was designed to overcome some of these deficiencies by comparing the performance of 20 oximeters with *in vitro* measurements of haemoglobin saturation using a four wavelength co-oximeter in patients after cardiac surgery involving cardiopulmonary bypass and hypothermia. Such patients have been shown by Kuttila to have poor peripheral perfusion.[8] In Kuttila's studies peripheral perfusion measured by skin red cell flux did not return to normal until rectal temperature had increased to 37.5°C. Reperfusion of the peripheral vascular bed was delayed until 7 hours after surgery.[8]

Methods

Patient selection

The study was approved by the local Human Ethics Committee. Adult patients were studied 30 minutes to 2 hours after transfer from the operating theatre to the cardiac surgery recovery ward, and all had undergone surgery involving cardiopulmonary bypass with hypothermia to 25–31°C. All patients were sedated and were undergoing intermittent positive pressure ventilation of the lungs at the time of the study.

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Accepted 15 July 1990.

0003–2409/91/010003+08 $03.00/0

Observations

The age, sex, operation, rectal temperature, systolic, diastolic and mean blood pressures and drug therapies of each patient were recorded.

The performance of 20 pulse oximeters was studied. They were supplied by their manufacturers and were checked for compliance with the Australian Standard 3200-1986 on electromedical equipment for use in patient care areas.

Pulse oximeter probes were placed on patients' fingers according to the manufacturers' instructions. Systemic arterial pressures were monitored directly and continuously through radial artery cannulae. Pulse oximeter probes were applied only to fingers on the arm not bearing the arterial cannula. Probes were not applied to the thumb. The finger used for each manufacturer's probe was varied in a predetermined fashion to ensure that each probe was placed an equal number of times on each of the fingers used, and so that any possible systematic interference from adjacent probes was eliminated. A two-dimensional matrix was constructed after allocating a number to each oximeter and a letter to each finger so that it could be visually checked that these requirements were met. All probes were covered by opaque rubber sleeves to reduce the likelihood of cross-over radiation, and were allowed to stabilise for 3 minutes before observations were made.

The haemoglobin saturation and pulse rate displayed on oximeters were recorded. A 2-ml sample of heparinised arterial blood was taken at the same time from the indwelling radial artery cannula. It was noted when pulse oximeters failed to give readings of haemoglobin saturation.

The 20 pulse oximeters were arranged on three trolleys in the groups given below.

Group 1 *Datex Satlite* (Datex Instrumentarium Corp. Helsinki, Finland)
Invivo 4500 (Invivo Research Laboratories, Broken Arrow, Oklahoma, USA)
Nellcor N-200 (Nellcor Incorporated, Hayward, California, USA)
Novametrix 505 (Medical Systems Inc., Wallingford, Connecticut, USA)
Ohmeda Biox 3740 (Ohmeda, Boulder, Colorado, USA)
Radiometer Oximeter (Radiometer A/S, Copenhagen, Denmark)

Group 2 *Datascope Accusat* (Datascope Corp. Paramus, New Jersey, USA)
Ohmeda Biox 3700 (Ohmeda, Boulder, Colorado, USA)
Nonin 8604D (Nonin Medical, Inc., Plymouth, Minnesota, USA)
Physio-Control 1600 (Physio Control, Redmond, Washington, USA)
Sensormedics Oxyshuttle (SensorMedics Corporation, Anaheim, California, USA)
Simed S-100 (Simed Corporation, Bothell, Washington, USA)
Spectramed Pulsat (Spectramed Inc., Oxnard, California, USA)

Group 3 *Biochem Microspan 3040* (Biochem International Inc., Waukesha, Wisconsin, USA)
Criticare CSI 503 (Criticare Systems, Milwaukee, Wisconsin, USA)
Criticare CSI 504 (Criticare Systems, Milwaukee, USA)
Engstrom Eos (Gambro Engstrom AB, Bromma, Sweden)
Kontron 7840 (Kontron Instruments, Watford, UK)
Minolta Pulsox 7 (Minolta Camera Co., Osaka, Japan)
Pulsemate Colin BX-3 (Nippon Colin Co., Hayashi, Japan)

Each of 40 patients was tested by every oximeter on of these trolleys. There were more oximeters than fing available for each test, so haemoglobin saturation measured twice in each patient by pulse oximetry arterial blood co-oximetry. Each pulse oximeter was tes once on 40 different patients. The oximeters were alter tively tested on the first or second run for each patient that the possibility of any systematic bias against a par ular oximeter was eliminated. The three groups oximeters were tested sequentially in the order given.

Co-oximetry and arterial blood gas analysis

Arterial blood samples were collected anaerobically, sto on ice and analysed by co-oximeter (IL - Instrumentation Laboratory, Lexington, Massachuse USA). Samples were analysed within one hour of col tion. The co-oximeter was calibrated weekly against manufacturer's 'Cal Dye' solutions of known haemoglo concentration. Three test solutions of preserved blood known saturations supplied by Instrumentat Laboratories were analysed daily to confirm that the formance of the machine was within specification. procedures were performed according to the manu turer's instructions.

Statistical analysis

Descriptive statistics were calculated for all pulse oximet studied and for the three groups of 40 patients tested usi the three groups of pulse oximeters. Comparisons betwe patient groups were made using a commercial statist package (Statgraphics, Statistical Graphics Corporati Rockville, Maryland, USA) and analysis of varian (Scheffe method for parametric data and Kruskal–Wa method for nonparametric data). Statistical significan was accepted when $p < 0.05$.

The co-oximeter measurement was subtracted from corresponding haemoglobin saturation displayed by ea pulse oximeter to give the difference (bias) of pu oximeter from co-oximeter measurement. The mean these differences was taken as the mean bias (accurac Precision was taken to be one standard deviation of differences between the pulse oximeter and the co-oximet

Results

One hundred and twenty patients were studied. The me and standard deviations of the measurements made on 120 patients are given in Table 1. The means and standa deviations of the 40 observations made when each gro was tested appear in Table 2. Analysis of variance show no significant differences between the groups with resp

Table 1. Means and standard deviations of measurements made on all patients ($n=120$). Co-oximetry was performed twice on each patient ($n=240$).

Measurement	Mean	SD
Age (years)	60	9.4
Rectal temperature (°C)	35.1	0.75
Systolic arterial pressure (mmHg)	114	15.4
Diastolic arterial pressure (mmHg)	59	9.4
Pulse pressure (mmHg)	55.4	15.6
Heart rate (beats/minute)	96	16.2
Haemoglobin saturation %	96.7	1.7
Carboxyhaemoglobin %	2.0	0.54
Methaemoglobin %	0.5	0.39

to age, rectal temperature, heart rate, co-oximeter oxygen saturation, carboxyhaemoglobin, methaemoglobin and blood gas machine bicarbonate and oxygen saturation. Differences between patients with respect to systolic and diastolic arterial pressures were significant at the 5% level. However, differences in pulse pressures between the three groups were not significant. Given that the mean systolic and diastolic blood pressure were all within the normal clinical range, and that there was no difference in pulse pressure, no bias toward any particular trolley should have been caused by the small differences in systolic and diastolic pressures between the trolleys.

Table 2. Means and standard deviation on three groups of 40 patients tested sequentially using three groups of oximeters. Analysis of variance (ANOVA) at 2117 degrees of freedom: F statistic and significance level, p. (* = $p<0.05$)

Measurement	Mean	SD	
Age (years)			
Group 1	60.5	8.6	ANOVA
Group 2	61.2	10.1	F=0.25
Group 3	59.7	9.6	p<0.8
Rectal temperature (°C)			
Group 1	35.1	0.85	ANOVA
Group 2	35.1	0.73	F=0.29
Group 3	35.2	0.66	p<0.8
Systolic arterial pressure (mmHg)			
Group 1	118	15.9	ANOVA*
Group 2	109	14.4	F=3.96
Group 3	116	14.3	p<0.02
Diastolic arterial pressure (mmHg)			
Group 1	60.2	10.0	ANOVA*
Group 2	55.9	7.6	F=3.29
Group 3	60.8	10.1	p<0.04
Pulse pressure (mmHg)			
Group 1	57.4	16.9	ANOVA
Group 2	53.0	14.0	F=0.79
Group 3	55.7	16.2	p<0.45
Heart rate (beats/minute)			
Group 1	96.3	13.3	ANOVA
Group 2	94.5	19.4	F=0.36
Group 3	97.9	15.6	p<0.7
Co-oximeter			
Haemoglobin saturation (%)			
Group 1	97.0	0.91	ANOVA
Group 2	96.5	1.59	F=1.31
Group 3	96.5	2.14	p<0.3
Carboxyhaemoglobin (%)			
Group 1	2.0	0.44	ANOVA
Group 2	2.1	0.52	F=0.11
Group 3	2.0	0.65	p<0.9
Methaemoglobin (%)			
Group 1	0.48	0.31	ANOVA
Group 2	0.48	0.57	F=2.25
Group 3	0.66	0.35	p<0.1

Most of the oximeters failed to give a reading on a number of patients as a result of poor signal quality. This drop-out rate was expressed as the percentage of tests for which a pulse oximeter gave no reading because of low quality signals. The ability to recognise a weak or very noisy waveform which could cause an erroneous saturation reading is a safety feature of all the models used in this trial. Instead of showing saturation the oximeter display is blank, or it may display a flashing value or a message which indicates a poor quality signal. Five of the 20 oximeters tested gave readings on all 40 patients (Fig. 1). The number of readings within 2% of the co-oximeter ranged from 11 to 32, while the number of readings within 3% of the co-oximeter ranged from 20 to 40 (Fig. 1). The number of readings within 3% of the co-oximeter reading was expressed as a percentage of the total readings and ranged from 100% down to 57% (Table 3).

The mean difference (accuracy) of the pulse oximeters differed by 0.1 to 4.5% haemoglobin saturation from co-oximeter values. Pulse oximeters varied from underestimating haemoglobin saturation by a mean of 4.5 % to overestimating it by a mean of 2.7% (Fig. 2). Sixteen pulse oximeters tended to overestimate haemoglobin saturation and four underestimated it. Differences in precision between oximeters that overread and underread haemoglobin saturation reached statistical significance. The precision, or standard deviation of the differences between pulse oximeter and co-oximeter, varied from 0.96% to 5.78% (Fig. 3).

We can determine the 95% confidence limits (mean $\pm 1.96 \times$ SD) within which we would expect 95% of the readings of the pulse oximeters to fall by use of the individual values for bias and precision. These are displayed in Figure 4. The upper and lower limits of these ranges are not equidistant from zero.

There was no significant difference between the three trolleys with respect to ranking for accuracy, precision, drop-out rate, $\pm 3\%$ values, $\pm 2\%$ values, 95% positive limits or final overall combined ranking using Kruskal–Wallis analysis of variance.

Discussion

Manufacturers specify commonly that pulse oximeters have a standard deviation, when compared to a 'gold standard' of 1.5–2.5% (greater than 75% of units we tested state 2%) at saturations in the range 90–100%. One interpretation of this is that 95% of readings should be within 1.96 times the standard deviation (4% saturation in the majority) of the true value. Only two out of the 20 pulse oximeters met this criterion, with one additional oximeter meeting its manufacturer's (but not this) specification. The algorithms used to process the plethysmographic signal electronically are compared with co-oximetry data during development. Few human data of haemaglobin saturations below 70% are available and the accuracy claimed by manufacturers below 70–100% saturation is often less than 2%: these findings were confirmed in several comparative studies of oximeters,[2-9] and will be summarised and reviewed in the second paper of our series on potential sources of pulse oximeter error.

This study differs from previous studies in two respects. Firstly, a greater number of oximeters was available for study. Secondly, instead of investigating the oximeters on

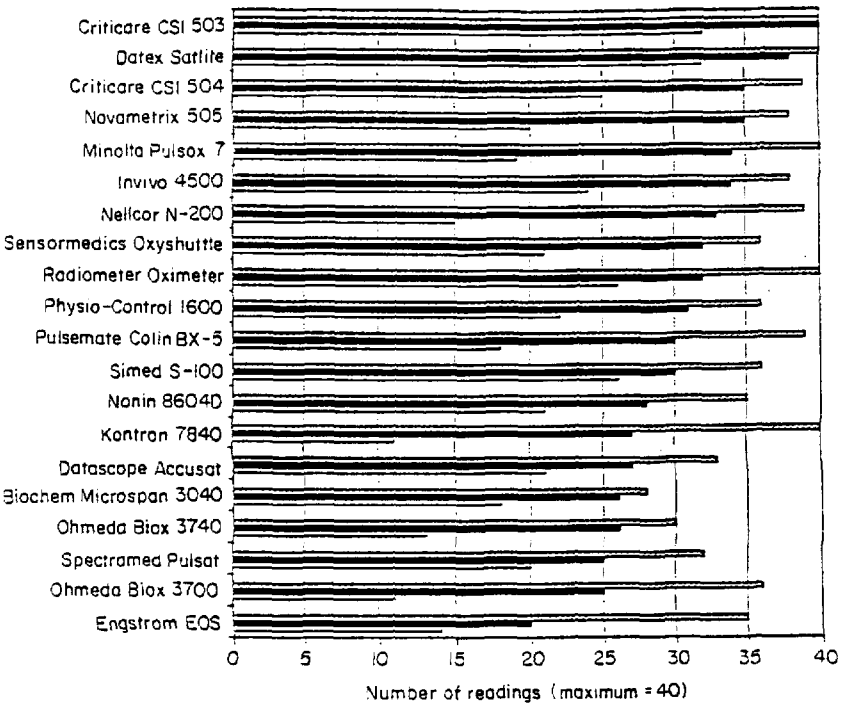

Fig. 1. The total number of readings and those within ±3 and ±2% of the co-oximeter reading. Each pulse oximeter was tested on 40 patients. ▨, total; ■, ±3%; □, ±2%

volunteers or warm, well-perfused patients, we examined only poorly perfused patients in the hope that this would prove to be a more discriminative model.

We have been able to verify the poor perfusion status of our patient population by comparing the drop-out rate for these patients with that for a better perfused population. Fourteen of the pulse oximeters used in this study were also used for a similar trial which involved intensive care unit patients, in which the oximeters were assessed by the same investigators using the same basic protocol described in this paper. The average drop-out rate for the intensive care unit patients was 0.26%, whereas that in this study was 8.7% that is 33 times higher, and reflects the relatively poor perfusion status of patients in this study.[9]

Table 3. Accuracy of pulse oximeters, ranked according to number of readings within 3% and showing ranking for number of readings within 3% of total number of readings expressed as percentage.

Oximeter	Total	±3%	Percent ±3%/total	Rank
Criticare CSI 503	40	40	100	1
Datex Satlite	40	38	95	2
Novametrix 505	38	35	92	4
Criticare CSI 504	39	35	90	5
Invivo 4500	38	34	89	6
Minolta Pulsox 7	40	34	85	10
Nellcor N-200	39	33	85	10
Sensormedics Oxyshuttle	36	32	89	6
Radiometer Oximeter	40	32	80	14
Physio-Control 1600	36	31	89	6
Simed S-100	36	30	83	12
Pulsemate Colin BX-5	39	30	77	17
Nonin 8604D	35	28	80	14
Kontron 7840	40	27	68	19
Datascope Accusat	33	27	82	13
Biochem Microspan 3040	28	26	93	3
Ohmeda Biox 3740	30	26	87	9
Spectramed Pulsat	32	25	78	16
Ohmeda Biox 3700	36	25	69	18
Engstrom Eos	35	20	57	20

Morris *et al.* compared 15 oximeters under conditions of poor perfusion.[5] This study may be criticised on two counts. Firstly, rather than using a saturation measured by co-oximeter as their 'gold standard' they used an arbitrarily chosen oximeter on the contralateral arm. Secondly, poor peripheral perfusion was produced by occlusion using a pneumatic tourniquet. This model clearly differs from poor peripheral perfusion in the postoperative cardiac patient and it was suggested that it represents venous occlusion. Other workers[2,7,10] have examined how various oximeters perform when peripheral perfusion is reduced, but examined only small numbers of oximeters. Tremper concluded that pulse oximeters are sufficiently accurate for clinical purposes over a wide range of haemodynamic conditions but examined only the Biox III Ohmeda oximeter.[10]

Wilkins *et al.* studied four pulse oximeters under conditions of venous engorgement caused by inflation of a sphygmomanometer cuff to 40 mmHg and vasoconstriction induced by placing the subject's arm in a cold water-filled plastic envelope.[7] They found that under both experimental conditions the detection time for induced hypoxaemia was significantly increased. They noted in addition marked differences in the oximeters tested both in their susceptibility to vasoconstriction and venous congestion and in their ability to detect desaturation. One deficiency in the study was that each oximeter acted as its own control and no reference saturation, such as that measured by a co-oximeter, was used. Thus no measure of absolute accuracy was given for the oximeters under test. The application of venous engorgement is, as in the study of Morris *et al.*,[5] of doubtful clinical validity.

One recent paper[11] examined two pulse oximeters on patients immediately after open heart surgey. The lower

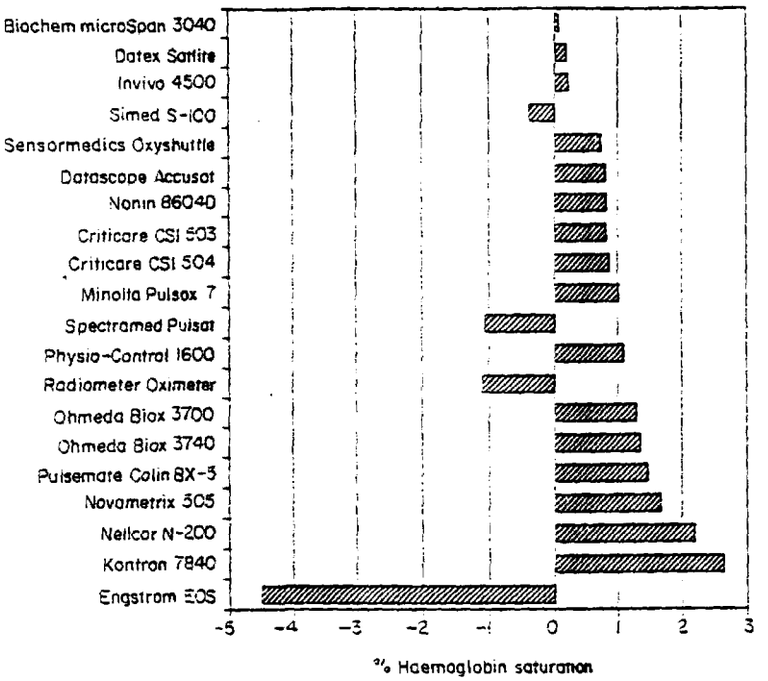

Fig. 2. Pulse oximeter brands ranked by accuracy, or mean of the differences between the pulse oximeter readings and the co-oximeter readings.

cardiac index and temperature at which readings were obtained were 2.4 (litres/minute)/sq m and 26.5°C respectively. Great interindividual variability was characteristic of all variables and equipment studied.

Our results show that under conditions of poor perfusion only two oximeters would be expected to give readings within 4% of our reference co-oximeter 95% of the time. These were the Datex Satlite and Criticare CSI 503. Six would be expected to give readings within 5%. These were the Invivo 4500, Novametrix 505, Simed S-100, Nellcor N-200, Physio-Control 1600 and Kontron 7840. Eight would be expected to give readings within 6%. These were the Sensormedics Oxyshuttle, Datascope Accusat, Radiometer OXI, Minolta Pulsox 7, Biochem Microspan 3040, Nonin 8604D, Criticare CSI 504 and Pulsemate Colin BX-5. The final four would be expected to give

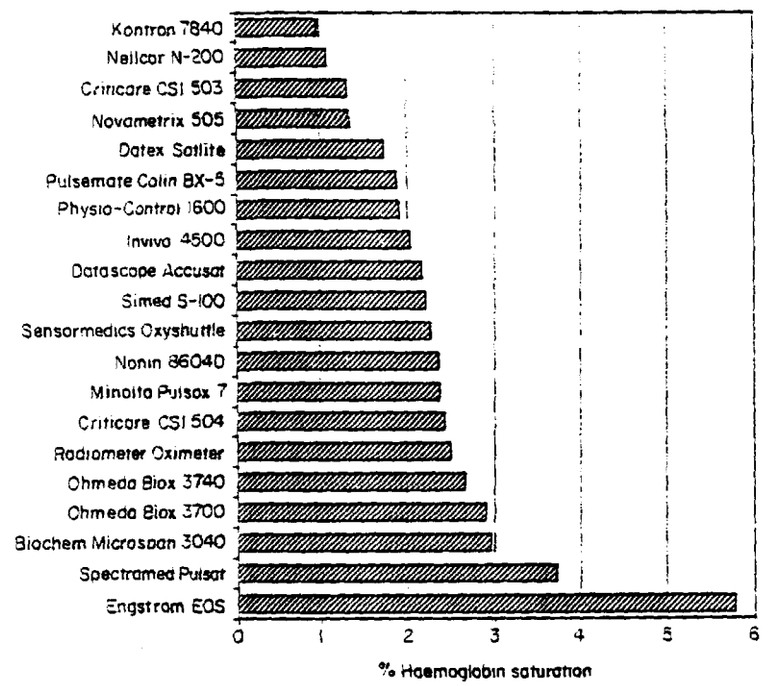

Fig. 3. Pulse oximeter brands ranked by precision, or standard deviation of the differences between the pulse oximeter readings and the co-oximeter readings.

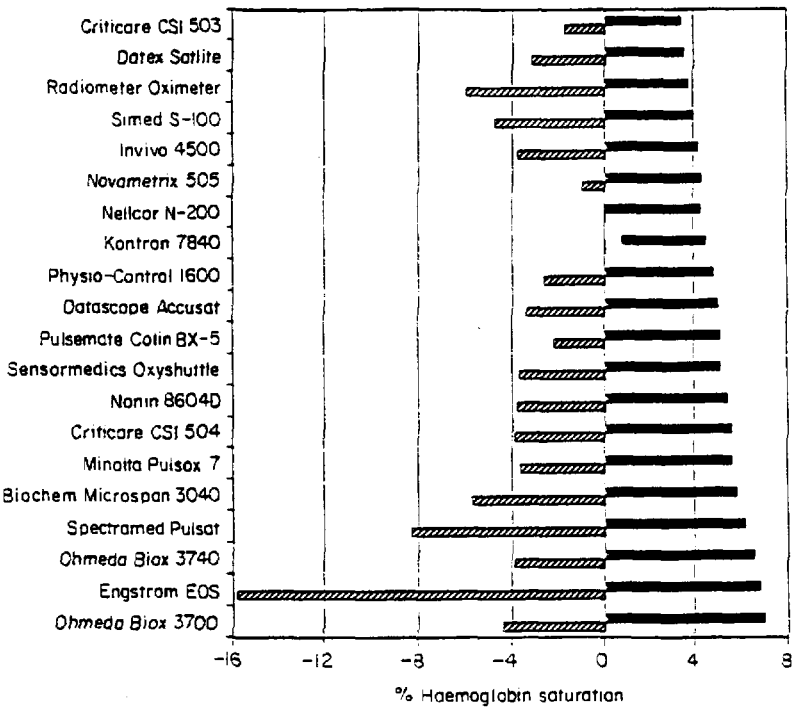

Fig. 4. The 95% limits for each pulse oximeter, with the brands ranked by positive limit.

readings outside these ranges. These were the Ohmeda Biox 3700 and 3740, Spectramed Pulsat and Engstrom Eos. It can be seen that oximeters that performed well tended to overread while some of those that performed poorly, in particular the Engstrom Eos, tended to underread. It may be argued that underreading is safer than overreading since the clinician will react more readily to desaturation, but this does not vindicate the poor overall performance of some of the oximeters studied.

Oximeters gave no reading in 8.7% of measurements. Ten of the 20 oximeters failed to give readings at least 10% of the time.

Whenever a comparative study is performed with a large number of devices there is always a certain amount of pressure exerted upon those performing the study to rank the devices according to some chosen criteria. This is especially so with a device such as the pulse oximeter which is used in acute care clinical situations, cannot be easily calibrated, and if it performs poorly, can lead to patient harm. It is also important to distinguish between assessment of the performance of the device with respect to the manufacturer's specifications, which in this case would be that 95% of values are within 4% of the true value, and performance with respect to clinically acceptable accuracy, which in this study was designated as within 3% of true value. Some clinicians may be unhappy accepting an error of 3%, since a pulse oximeter reading of 93% saturation would mean the patient had a possible arterial oxygen tension of between 59 and 85 mmHg.

The first difficulty is in the choice of criteria to be used for the ranking. One obvious criterion is the accuracy of the device when compared with the best available 'gold standard'. An average difference between the reading given by the pulse oximeter and that given by the co-oximeter is such an example. The pulse oximeters can then be ranked according to the magnitude of that difference (Fig. 2). This raises the question of whether the differences should be used or whether, as in the case of the pulse oximeter, device that overreads should be ranked lower than one th 'fails safe' and underreads.

Another criterion is the precision or reproducibility the measurements. This is determined by the standar deviation of the differences between the pulse oximeter an the co-oximeter and again the pulse oximeters can b ranked in order from smallest to largest standard deviatio (Fig. 3).

The pulse oximeters varied quite markedly in the ranking for these two criteria. The Biochem Microspa 3040 ranked number one in terms of accuracy but on number 18 in terms of precision. This means that the were quite wide swings about the true value and while th average difference was small, an individual reading woul have a high chance of being inaccurate. On the other hand the Kontron 7840 ranked number one in terms of precisio but only ranked number 19 in terms of accuracy. If a offset of −2.65% were applied to the algorithm used in th Kontron 7840 then it would have ranked highest overall o the pulse oximeters tested with respect to accuracy an precision.

The 'gold standard' used in this study was the IL 482 co-oximeter (Lexington, MA, USA). This gives an oxyhaemoglobin saturation (fractional saturation), and thus may tend to favour devices such as the Ohmeda which is calibrated against fractional saturation rather than the Nellco which is calibrated to give functional saturation. The precision (SD) information would, however, be unaffected; th argument for evaluation of pulse oximeter performanc against fractional saturation is discussed in detail in th companion paper.[12]

We also examined the number of readings that each uni gave out of the 40 patients tested in this study. There again the problem of how these results should be ranked. I can be seen from Figure 1 that some of the units gav readings for all 40 patients but the percentage of thes

Table 4. Pulse oximeter brands ranked on a combination of accuracy, precision, number of readings within 3% and positive limit.

Oximeter	Accuracy	Precision	±3%	Percent	Positive limit	Combined
Datex Satlite	2	5	2	2	2	13
Criticare CSI 503	8	3	1	1	1	14
Invivo 4500	3	8	5	6	5	27
Novametrix 505	17	4	3	4	6	34
Simed S-100	4	10	11	12	4	41
Sensormedics Oxyshuttle	5	11	8	6	12	42
Nellcor N-200	18	2	7	10	6	43
Physio-Control 1600	12	7	10	6	9	44
Criticare CSI 504	9	14	3	5	14	45
Datascope Accusat	6	9	14	13	10	52
Radiometer Oximeter	13	15	8	14	3	53
Minolta Pulsox 7	10	13	5	10	15	53
Biochem Microspan 3040	1	18	16	3	16	54
Nonin 8604D	7	12	13	14	13	59
Pulsemate Colin BX-5	16	6	11	17	11	61
Kontron 7840	19	1	14	19	8	61
Ohmeda Biox 3740	15	16	16	9	18	74
Spectramed Pulsat	11	19	18	16	17	81
Ohmeda Biox 3700	14	17	18	18	20	87
Engstrom Eos	20	20	20	20	19	99

readings that were of acceptable accuracy (within 3%) varied enormously. How should we rank the results of this part of the study? We attempted to do this by ranking the pulse oximeters in order according to how many readings out of the 40 were within 3% of the co-oximeter (see Fig. 1). We also calculated the percentage of readings, out of the total readings given, that were within 3% of the co-oximeter. The pulse oximeters were then ranked according to this result (see Table 3). This ranking is biased in favour of those units which may not have given as many results as some others, but when they did give a result, it was more likely to be of acceptable accuracy. One unit for example gave readings for all 40 patients but only 27 were within 3% of the co-oximeter (a percentage of 68, ranking of 19). Another unit only gave 28 readings but 26 were within 3% of the co-oximeter (a percentage of 93, ranking of 3).

The fifth method of ranking was to look at the highest positive error that 95% of the units readings would be expected to fail below (see Fig. 4). This makes the assumption that, from a clinical safety point of view, those units which make a lower positive error should be ranked higher than those that make a higher positive error.

We did not perform linear regression analysis and calculation of correlation coefficients for each of the pulse oximeters tested. The issue of which is the appropriate statistical method to interpret the data of methods-comparison studies[13–15] was addressed by Tremper[1] and we agree that calculation of means of difference between the pulse oximeters and the co-oximeter and the standard deviations of these differences gives the most meaningful information.

Other criteria, which include human factors design, alarms and indicators, electrical performance and safety, accuracy in the presence of interference, probe characteristics, operator's manual, quality of construction and ease of servicing, are considered in the Health Devices article by the Emergency Care Research Institute, in which some of the data from the 13 devices studied here and marketed in the USA also appears.[9]

How then should these rankings be combined? Table 4 shows that they were simply added together to give an overall ranking. Others may wish to add a weight to the various individual criteria before they are combined. All the rankings are presented for the five individual criteria (Table 4) for this reason, so that potential purchasers can 'weight' each ranking according to their own preferences.

This study was carried out using oximeters supplied with the then current software. It is likely that most manufacturers have since updated their software, and that the empirically adjusted 'read-out' values will correlate better with a typical group of patients.[12] Nevertheless, this study emphasises that there may be important differences between pulse oximeters, and that further comparative evaluations of pulse oximeters will be necessary.

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