

## COMPARISON OF PULSE OXIMETERS: ACCURACY AT LOW ARTERIAL PRESSURE IN VOLUNTEERS

R. J. FALCONER AND B. J. ROBINSON

### SUMMARY

*A laboratory model was developed of limb hypoperfusion in volunteers, using partial occlusion of the brachial artery with consequent reduction in radial artery pulse pressure. This was used to compare the function of 13 pulse oximeters and the effect of reduced pulse pressure and mild hypoxia on these devices. With the exception of one device, all the pulse oximeters studied demonstrated similar accuracies at pulse pressures exceeding 20 mm Hg. There were however, significant differences between several of the pulse oximeters in both ability to display readings and accuracy of readings displayed when brachial artery occlusion reduced radial artery pulse pressures equal to or less than 20 mm Hg.*

### KEY WORDS

*Equipment: pulse oximeters. Monitoring: pulse oximeters, arterial pressure.*

The reliability of pulse oximetry measurements may be affected by factors which include the nature of the haemoglobin present (e.g. methaemoglobin, carboxyhaemoglobin), movement artefacts and low peripheral perfusion. Several studies have assessed the accuracy of pulse oximeters in volunteer subjects during induced desaturation [1, 2] and in neonates [3] and adults [4]. Other studies have assessed the accuracy of pulse oximeters and the effects of peripheral hypoperfusion both in volunteers [5-7] and in patients immediately after open heart surgery [8, 9]. However, the methods used may be inappropriate; volunteer studies which use arterial tourniquets to reduce the pulse pressure [5, 6] are of doubtful validity. Venous congestion caused by the tourniquet can cause pulsatile venous flow which may be detected by the pulse

oximeters as arterial pulsation and result in falsely low readings of "arterial" saturation [10]. One other study has compared pulse oximeters using cold-induced peripheral vasoconstriction (cold-pressor response) [7]. This model may not be representative of the cardiovascular events that occur during operative procedures as there is no concomitant reduction in cardiac output and there is an increase in arterial pressure. In studies of patients after cardiac bypass [8, 9], there may also be problems with temperature dependent changes in performance of the LED and photodetector components of the pulse oximeter probe [11]. Also, any reduction of arterial pressure in these patients is uncontrolled and there may be pathological changes in the peripheral circulation of some.

In this study we describe a laboratory model of limb hypoperfusion by partial occlusion of the brachial artery which avoids venous congestion. We used this model, combined with mild hypoxia induced by breathing hypoxic gas mixtures, to compare in healthy volunteers the accuracy of several currently available pulse oximeters.

### SUBJECTS AND METHODS

The study was approved by the Wellington Hospital Board Ethics Committee. Informed consent was obtained from nine volunteers aged 25-45 yr (two female, seven male; eight Caucasian, one Chinese). Three of the volunteers participated on two occasions 5, 13 and 14 weeks apart. One of the volunteers participated on three

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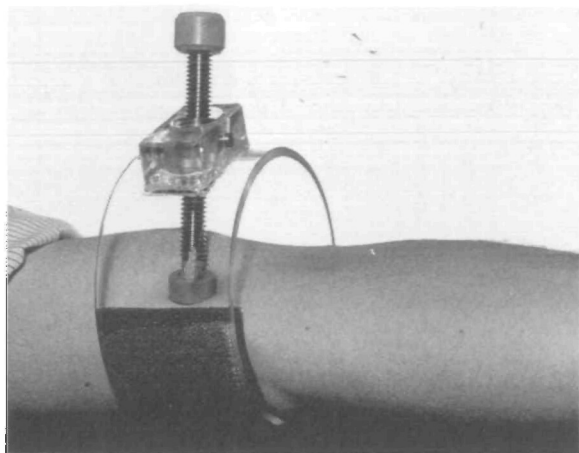


Fig. 1. Device for occluding the brachial artery.

occasions separated by intervals of 7 and 10 weeks, respectively. All other volunteers participated on one occasion. Volunteers were excluded if they had a history of cardiovascular disease, smoked within the previous 48 h, or had an aberrant arterial configuration at the wrist as demonstrated by Allen's test.

A 22-gauge cannula was inserted into the radial artery of the non-dominant hand under local anaesthesia for blood sampling and for direct measurement of arterial pressure (Hewlett-Packard; model 1029A transducer, model 78342A monitor). Arterial pulse pressure was reduced during the study by using a specially made clamp which encircled the arm at the elbow and pressed a disc (22 mm diameter) onto the skin over the brachial artery (fig. 1). This clamp was threaded so that the degree of arterial compression and occlusion could be adjusted, leading to a controlled reduction in arterial pressure, which was measured at the wrist. The pulse pressure (systolic pressure minus diastolic pressure) was used to quantify the degree of hand perfusion. The subjects were supine and the cannulated arm rested on a padded surface at heart level.

Pulse oximeter probes were attached randomly to different fingers of the subject. Probes were covered to prevent interference from adjacent probes and room lighting. Blood samples from the arterial cannula were drawn into heparinized syringes and  $Sa_{O_2}$  measured immediately using a co-oximeter (OSM 2 Hemoximeter, Radiometer Copenhagen). Immediately before each blood sample was taken, the  $Sa_{O_2}$  readings displayed by each pulse oximeter were recorded, with systolic

and diastolic arterial pressures displayed on the arterial pressure monitor. Recordings were repeated both under resting conditions and with occlusion of the brachial artery. Hypoxia was induced in the volunteer by breathing a hypoxic gas mixture (12–14% oxygen in nitrogen) from pre-filled 300-litre Douglas bags via a non-rebreathing valve. When hypoxia reached a steady state from the results of three serial arterial haemoglobin oxygen saturation determinations (all within 2%), further blood samples were taken at approximately 1-min intervals with simultaneous recordings of pulse oximeter readings and arterial pressure. Recordings were repeated with limb pulse pressure reduced. The subject remained hypoxic ( $Sa_{O_2}$  between 88% and 80%) for several minutes and achieved resaturation between sets of recordings by breathing 100% oxygen. At approximately 20-min intervals, the pulse oximeter probes were removed for 5 min to avoid gradual compression of the fingers by the probes. After 5 min the probes were reattached so as to be tested in turn on each finger. The finger to which each probe was attached was noted.

Thirteen pulse oximeters were used in the study: Biochem 1040a, Criticare 504US, Critikon Oxyshuttle, Datex Satlite, Kontron 7840.2, Nellcor N100, Nellcor N200, Novamatrix 505, Ohmeda 3700, Physiocontrol 1600, Radiometer Oxi, Sein Se200, Simed S100. Not all pulse oximeters were tested on all subjects. Wherever possible, pulse oximeters were set up with the fastest  $Sa_{O_2}$  display averaging times (e.g. 3 s) active. When the Nellcor N200 was used with the ECG cable attached to the volunteer (Nellcor N200+ecg), a semi-disposable probe (N-25) was used as requested by the manufacturer; otherwise a standard finger probe was used when this unit was used without the ECG (Nellcor N200–ecg). The Criticare 504US was evaluated also with (Criticare 504US+ecg) and without (Criticare 504US–ecg) the ECG cable attached to the volunteer. The Radiometer Oxi was used only with a multi-site flex probe. With all other pulse oximeters the standard multi-use finger probe was used. One pulse oximeter unit was evaluated for each model tested with the exception of the Nellcor N200–ecg and Simed S100 for which two units of both were evaluated. Although the software was different for the units of both models, there was no significant difference between the results of each model and therefore data were combined.

TABLE I. Numbers of observed and expected correct, incorrect and missing readings for the Seín SE200 pulse oximeter.  $\chi^2$  was calculated from the observed and expected correct, incorrect and missing readings except at \*pulse pressures greater than 10 mm Hg, for which incorrect and missing readings were combined since the values in some of these cells were less than 5

Pulse pressure (mm Hg)	Total observations	Correct			Incorrect			Missing		
		Observed	Expected	$\chi^2$	Observed	Expected	$\chi^2$	Observed	Expected	$\chi^2$
≤ 10	133	25	74.4	32.8	70	40.7	21.09	38	18.2	21.54
> 10 to ≤ 20	45	7	26.8	14.63	32	16.2	20.34*	6	2.0	*
> 20	88	24	60.8	22.7	63	27.0	50.16*	1	0.02	*

TABLE II. Pulse oximeter performance at pulse pressures equal to or less than 10 mm Hg.  $\chi^2 = (\text{Observed} - \text{expected})^2 / \text{expected}$ . Values of  $\chi^2 > 3.83$  may be considered significant ( $P < 0.05$ )

Pulse oximeter	Total observations	Correct			Incorrect			Missing		
		Observed	Expected	$\chi^2$	Observed	Expected	$\chi^2$	Observed	Expected	$\chi^2$
Biochem 1040a	115	67	59.3	1.00	40	39.6	0.23	8	16.1	4.08
Datex Satlite	180	127	97.0	9.28	47	50.8	0.28	6	32.1	21.22
Criticare 504US + ecg	62	42	33.6	2.10	20	20.0	0.00	0	8.4	8.40
Criticare 504US - ecg	49	34	36.0	0.06	15	10.3	2.14	0	2.1	2.10
Critikon Oxyshuttle	195	124	127.6	0.10	52	48.3	0.28	19	18.8	0.00
Kontron 7840.2	162	131	111.3	3.49	31	32.3	0.05	0	18.4	18.40
Nellcor N100	193	55	92.5	15.20	60	54.3	0.60	78	45.0	24.20
Nellcor N200 + ecg	99	74	64.0	1.56	24	24.9	0.03	1	9.1	7.21
Nellcor N200 - ecg	35	5	11.8	3.92	3	12.5	30.01	27	10.9	23.78
Novamatrix 505	215	124	121.2	0.06	29	32.7	0.42	62	58.2	0.25
Ohmeda 3700	144	82	71.4	1.57	48	39.5	1.83	14	33.0	10.94
Physiocontrol 1600	141	48	62.4	3.32	17	43.3	15.97	76	36.3	43.42
Radiometer Oxi	36	12	9.6	0.60	24	13.0	9.31	0	14.4	14.40
Simed S100	183	100	115.1	1.98	52	47.6	0.04	31	20.0	6.05

### Statistics

The results were categorized according to whether the pulse oximeter reading was correct (within 3% of the arterial blood sample), incorrect (outside 3% of the blood sample) or missing (no reading given). An  $Sa_{O_2}$  accuracy of "within 3%" was calculated from the variance of reported accuracy of the pulse oximeter and co-oximeter manufacturer's specifications; both device types have an accuracy of 2% at  $Sa_{O_2}$  values greater than 80%. The variance was calculated as:

$$\sqrt{2\% ^2 + 2\% ^2} = \sqrt{8\%} = 2.83\%.$$

Using the results of two pulse oximeters (Datex Satlite and Critikon Oxysuttle) from all nine subjects, there were marked differences between subjects at low (equal to or less than 20 mm Hg) pulse pressures in the number of correct, incorrect and missing readings. Therefore the numbers of expected correct, incorrect and missing readings were calculated for each subject, under the hypothesis that there were no differences between devices, for pulse pressures greater than 20 mm Hg, 11–20 mm Hg or equal to or less than 10 mm Hg. This was calculated from the total number of observed correct, incorrect and missing readings for all devices for each subject. The number of expected and the number of observed correct, incorrect and missing readings were summed across all subjects for each device. The numbers of expected and observed readings were compared using chi-square, with  $\chi^2 > 3.83$  considered significant (i.e.  $P < 0.05$ ).

### RESULTS

We collected 3509 individual data points. The Sein Se200 was found to operate in an extremely erratic manner, despite no occlusion of the brachial artery (table I). As it had not been used on all subjects, inclusion of its data distorted the expected observations of correct, missing and incorrect readings of some subjects and it was therefore eliminated.

Excluding the Sein Se200, there were no significant differences between the devices at pulse pressures greater than 20 mm Hg. At pulse pressures of 11–20 mm Hg the Physiocontrol 1600 gave fewer correct (observed 9, expected 17.5,  $\chi^2 = 4.13$ ) and more incorrect or missing (observed 11, expected 6.9,  $\chi^2 = 4.05$ ) readings than expected. There were no other differences between the devices at this pulse pressure.

At pulse pressures equal to or less than 10 mm Hg, significant differences were found between many of the devices (table II). The percentages of correct readings (within 3% of the co-oximeter measurement) more or fewer than expected at these pulse pressures are shown also in figure 2. The Datex Satlite was found to give more correct readings than expected ( $\chi^2 = 9.28$ ); the Nellcor N100 and N200-ecg gave fewer correct readings than expected ( $\chi^2 = 15.20$  and 3.92, respectively).

The percentages of incorrect readings (outside 3% of the co-oximeter measurement) are shown in figure 3. The Radiometer Oxi was found to give more incorrect readings than expected ( $\chi^2 = 9.31$ ). The Nellcor N200-ecg and Physiocontrol 1600 gave fewer incorrect readings than expected ( $\chi^2 = 30.01$  and 15.97, respectively).

The percentages of missing readings (no reading displayed on the oximeter) are shown in figure 4. The Radiometer Oxi ( $\chi^2 = 14.40$ ), Datex Satlite ( $\chi^2 = 21.22$ ), Criticare 504US+ecg ( $\chi^2 = 8.40$ ), Ohmeda 3700 ( $\chi^2 = 10.94$ ), Kontron 7840.2 ( $\chi^2 =$

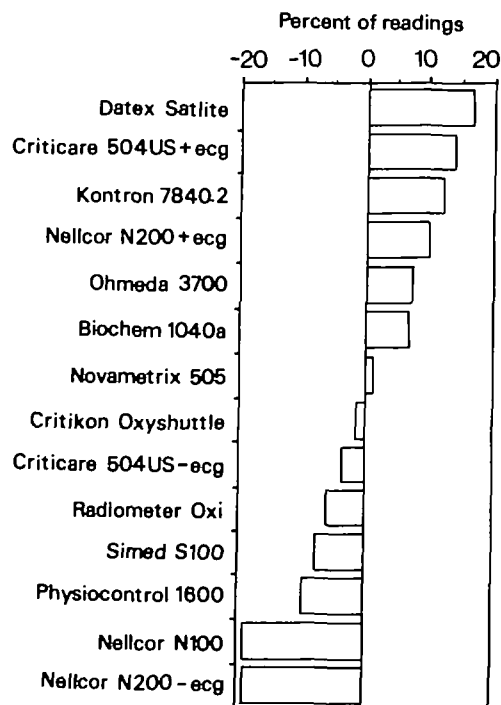


FIG. 2. Percentage of correct readings more (right of 0) or fewer (left of 0) than expected at pulse pressures equal to or less than 10 mm Hg for the pulse oximeters evaluated. The oximeters are ranked according to the percentage of correct readings more or fewer than expected.

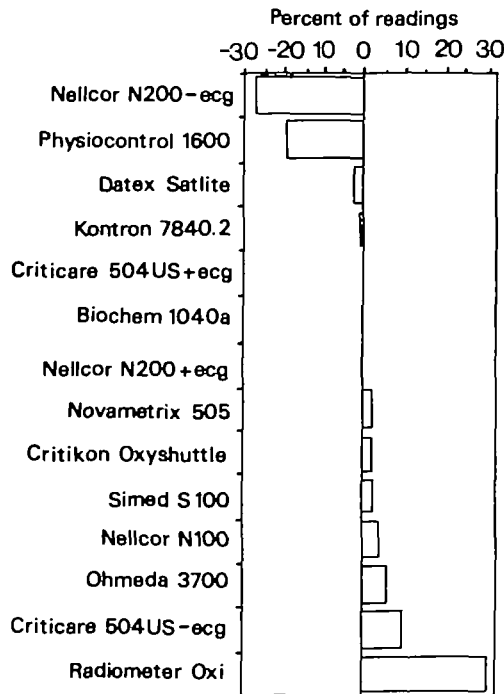


FIG. 3. Percentage of incorrect readings more (right of 0) or fewer (left of 0) than expected at pulse pressures equal to or less than 10 mm Hg for the pulse oximeters evaluated. The oximeters are ranked according to the percentage of incorrect readings more or fewer than expected.

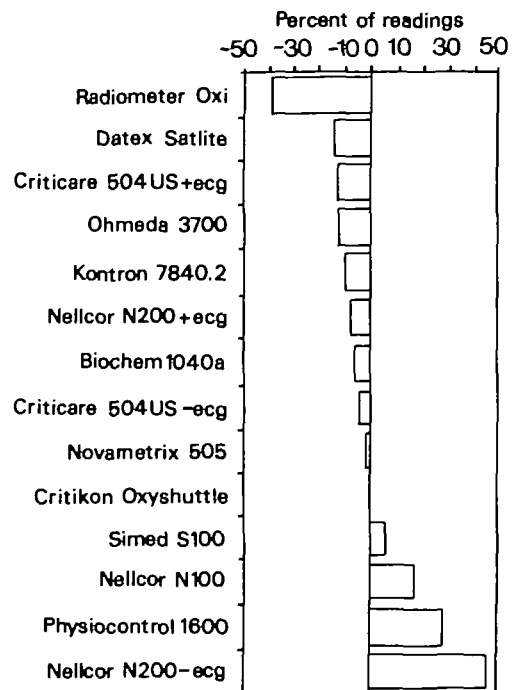


FIG. 4. Percentage of missing readings more (right of 0) or fewer (left of 0) than expected at pulse pressures equal to or less than 10 mm Hg for the pulse oximeters evaluated. The oximeters are ranked according to the percentage of missing readings more or fewer than expected.

18.40), Nellcor N200+ecg ( $\chi^2 = 7.21$ ) and Biochem 1040a ( $\chi^2 = 4.08$ ) were observed to miss fewer readings than expected. The Simed S100 ( $\chi^2 = 6.05$ ), Nellcor N100 ( $\chi^2 = 24.20$ ), Physiocontrol 1600 ( $\chi^2 = 43.42$ ) and Nellcor N200-ecg ( $\chi^2 = 23.78$ ) missed more readings than expected.

Studies were repeated on two or three occasions in four subjects. In all of these studies at least one pulse oximeter was used during two of the studies. Results obtained for a single pulse oximeter used on the same subject on the two occasions were comparable, suggesting the method is reproducible within subjects. We also ranked the function of each device according to the  $\chi^2$  values for correct, incorrect and missing readings from the group results and compared this with the ranking of the  $\chi^2$  values of the devices within individuals. The ranking of the devices from the grouped results was found to be comparable to the ranking of devices within individuals. The function of each pulse oximeter within subjects was not related to the finger used and was not affected by previous arterial cannulation.

#### DISCUSSION

We have created a simple model of peripheral hypoperfusion in volunteer subjects by partial occlusion of the brachial artery. This method reduces the arterial pressure which is measured directly at the radial artery and quantified by measuring the amplitude of the pulse wave (pulse pressure). Arterial blood samples were measured with a co-oximeter and mild hypoxia induced in volunteers in order to assess the accuracy of pulse oximeters during reduced blood flow to the probe site. The radial artery cannula did not affect the function of the pulse oximeters, as the accuracy of readings within individuals was not affected by the finger used. The number of repeated cannulations did not affect the function of the pulse oximeters, which suggests that no significant radial artery obstruction was present when the repeat studies occurred.

Brachial artery occlusion reduces the pulse pressure and thus there is a reduction in the size of the signal (i.e. pulse pressure wave) that the

pulse oximeters use to calculate the  $Sa_{O_2}$ . This situation is similar to that observed in patients with reduced cardiac output, hypotension or peripheral vasoconstriction. Previous studies investigating the effect of reduced blood flow on pulse oximeters have used arterial or venous tourniquets [5–7] which result in venous congestion. In these situations the inaccuracy of the devices is likely to be caused by increased noise (e.g. venous pulsation) in addition to a reduced signal. Although venous congestion may occur clinically, it is encountered rarely and the main concern of anaesthetists is to obtain reliable readings from a pulse oximeter when a patient has reduced arterial pressure or peripheral vasoconstriction. The reduction of pulse pressure in our volunteers is therefore more likely to simulate the adverse conditions for pulse oximetry encountered in clinical practice.

The Sein Se200 was found to function in an erratic manner despite no arterial occlusion. This device was significantly different from all other devices and its lack of accuracy at normal arterial pressures is of some concern.

Under the null hypothesis from the results of the pulse oximeters other than the Sein SE200 we were able to produce the profile for an "average" pulse oximeter against which to compare all the devices. There were statistically significant differences between many of the devices at pulse pressures less than 20 mm Hg. Many of the pulse oximeters functioned quite accurately to low arterial pressures, whereas other devices gave either inaccurate or missed readings. At pulse pressures equal to or less than 10 mm Hg, the Datex Satlite was found to be more accurate than the average pulse oximeter and, conversely, the Nellcor N100 and N200 – ecg were found to be less accurate. Although the Physiocontrol 1600 and Nellcor N200 – ecg gave fewer incorrect readings than the average pulse oximeter at pulse pressures equal to or less than 10 mm Hg, these devices also missed more readings than expected. This could be considered a desirable feature; lack of a reading is perhaps better than an inaccurate reading when a patient becomes hypotensive or has vasoconstriction. We also observed that the ECG synchronization improved the performance of the Criticare 504US and Nellcor N200, although

different probes were used in the latter device. The results of the Radiometer Oxi should be regarded with caution, as a standard finger probe was not available for evaluation with this device and the use of multi-site flex probe may have affected the accuracy of the device in this study.

From our results it is possible to rank devices according to each specific function. The ideal pulse oximeter should have as many correct readings with as few incorrect or missing readings as possible, and an overall ranking could be created by weighting the relative importance of each of these functions.

#### ACKNOWLEDGEMENT

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