Pulse oximeters demonstrate different responses during hypothermia and changes in perfusion

[Les sphygmo-oxymètres affichent des réponses différentes pendant l'hypothermie et les changements de perfusion]

Tomoki Nishiyama MD PhD

Purpose: Several new pulse oximeters using updated algorithms are marketed as being resistant to motion and hypoperfusion. The purpose of this study was to compare the performance of three pulse oximeters under conditions of hypothermia and altered perfusion.

Methods: Ten male volunteers were enrolled in this study after Institutional approval and obtaining informed consent. The probe of the Dolphin 2100, Nellcor N-595, or Masimo SET radical version 4.2 was attached to the left index finger. Time from 'power on' to acquire the pulse wave and oxygen saturation (SpO_2), time from the application of air tourniquet with 250 mmHg on the upper arm to loss of pulse wave and SpO_2, and time from the release of the tourniquet to acquire the pulse wave and SpO_2 were measured. Then, the patient's left hand and arm were cooled gradually to 27°C dermal temperature in a room at 19°C. The temperatures at loss of the pulse wave and SpO_2 were recorded.

Results: The Nellcor N-595 was the slowest to detect SpO_2 and pulse wave at 'power on'. The Masimo SET showed pulse wave and SpO_2 longer than the other two monitors after 'tourniquet on'. The Nellcor N-595 was the fastest to show pulse wave and SpO_2 following tourniquet release.

Conclusion: The Masimo SET was the slowest to respond to the changes in perfusion, and the Nellcor N-595 responded the fastest. However, the Nellcor N-595 was the slowest to show SpO_2 and pulse wave at 'power on'.

***Objectif** : De nouveaux sphygmo-oxymètres qui utilisent des algorithmes récents sont vendus comme insensibles au mouvement et à l'hypoperfusion. Nous avons comparé la performance de trois sphygmo-oxymètres dans des conditions d'hypothermie et de perfusion modifiée.*

***Méthode** : Dix volontaires masculins ont accepté de participer à l'étude approuvée par l'institution. La sonde du Dolphin 2100, du Nellcor N-595 ou du Masimo SET de version radicale 4,2 a été fixée à l'index gauche. Le temps écoulé depuis «la mise en marche» jusqu'à l'acquisition de l'onde pulsée et de la saturation en oxygène (SpO_2), depuis l'application du garrot sur le bras avec une pression de 250 mmHg jusqu'à la perte de l'onde pulsée et de la SpO2 et, enfin, depuis le retrait du garrot jusqu'à l'acquisition de l'onde pulsée et de la SpO_2 ont été mesurés. Puis, la main et le bras gauches ont été refroidis graduellement jusqu'à une température cutanée de 27 °C dans une pièce chauffée à 19 °C. La température a été notée au moment de la perte de l'onde pulsée et de la SpO_2.*

***Résultats** : Le Nellcor N-595 a été le plus lent à détecter la SpO_2 et l'onde pulsée au moment de «la mise en marche». Après la «pose du garrot», le Masimo SET a été plus lent que les deux autres moniteurs à montrer l'onde pulsée et la SpO_2. Le Nellcor N-595 a été le plus rapide à afficher l'onde pulsée et la SpO_2 après le relâchement du garrot.*

***Conclusion** : Le Masimo SET a été le plus lent à répondre aux changements de perfusion et le Nellcor N-595 le plus rapide. Par contre, le Nellcor N-595 a été le plus lent à montrer la SpO_2 et l'onde pulsée au moment de «la mise en marche».*

From the Department of Anesthesiology, Faculty of Medicine, The University of Tokyo, Tokyo, Japan.

Address correspondence to: Dr. Tomoki Nishiyama, 3-2-6-603, Kawaguchi, Kawaguchi-shi, Saitama, 332-0015, Japan. Phone: 81-3-5800-8668; Fax: 81-3-5800-9655; E-mail: nishit-tky@umin.ac.jp

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SEVERAL pulse oximetry manufacturers state that their new technologies are resistant to motion and hypoperfusion. There are some studies comparing the performance of pulse oximeters during motion.[1,2] However, it is very difficult to quantitate the speed and intensity of the quick finger motion to affect the performance of pulse oximeter in a clinical study. In contrast, changes of perfusion are easier to quantitate using the pressure of the tourniquet or blood pressure cuff,[3] or body or skin temperature at hypothermia.[4] Responsiveness to loss of blood flow or to reflow is also an important factor of pulse oximetry. In the present study, three pulse oximeters with the new technologies were compared with respect to their responses during hypothermia and altered perfusion.

Methods

After the approval of the Institutional Research Committee and obtaining informed consent, three pulse oximeters with their original probes were tested in ten male volunteers (41 ± 4 [SD] yr). The Dolphin 2100 (Dolphin Medical, Hawthorne, CA, USA), the Nellcor N-595 (Tyco Healthcare, Pleasanton, CA, USA), and the Masimo SET radical version 4.2 (Masimo, Irvine, CA, USA) were evaluated. Each volunteer was tested with each pulse oximeter on alternate days. The probe was attached to the left index finger. Time from 'power on' to acquire the pulse wave and the oxygen saturation (SpO_2), time from the application of air tourniquet (HE-8000, Helio Surgical, Tokyo, Japan) with 250 mmHg on the upper arm to loss of pulse wave and SpO_2, and time from the release of the tourniquet to acquire the pulse wave and SpO_2 again were measured. The air tourniquet could increase pressure to 250 mmHg or decrease pressure to 0 mmHg in one second, and the same tourniquet was used for all volunteers. Next, the left hand and arm of each subject were enveloped in a water blanket (MEDI-THERM II, GAYMAR, Orchard park, NY, USA) with the probe on the left index finger. The hand and arm were cooled gradually to 27°C at dermal temperature, measured at the left finger using a plate type probe of the MEDI-THERM II in a room at 19°C. The temperature at loss of the pulse wave and SpO_2 was recorded.

Data are shown as mean ± standard deviation. Statistical analysis was performed with the factorial analysis of variance followed by Student-Newman-Keuls test as a post-hoc test. A P value < 0.05 was considered to be statistically significant. A post-hoc power analysis was performed using the G power version 2.1.2 (University of Trier, Trier, Germany) with $\alpha = 0.05$, f = 0.25 for each measurement (total sample size = 30 for three groups).

Results

Summary data of the response times for each of the monitors are presented in the Table. Time from 'power on' to acquire the pulse wave was in the order of the Dolphin 2100 < Masimo SET < Nellcor N-595 ($P < 0.05$). Time from 'power on' to acquire SpO_2 was in the order of the Masimo SET < Dolphin 2100 < Nellcor N-595 ($P < 0.05$). Time from the tourniquet on to loss of the pulse wave was in the order of the Nellcor N-595 < Dolphin 2100 < Masimo SET ($P < 0.05$). Time from the tourniquet on to loss of SpO_2 was in the order of the Dolphin 2100 < Nellcor N-595 ($P < 0.05$) = Masimo SET. Time from the tourniquet off to acquire the wave and SpO_2 was in the order of the Nellcor N-595 < Dolphin 2100 < Masimo SET ($P < 0.05$), (Table). Cooling the hand and arm to 27°C took 325 ± 35 sec for the Dolphin 2100, 343 ± 55 sec for the Nellcor N-595, and 332 ± 47 sec for the Masimo SET. No disturbance of the measurement of SpO_2 was found for any monitor when the arm was cooled to 27°C. The power of this study was 0.195.

Discussion

In the present study, the Dolphin 2100 and the Masimo SET were faster in acquiring signals than the Nellcor N-595 at 'power on'. Therefore, in emergency cases, the Dolphin 2100 or the Masimo SET may be more useful than the Nellcor N-595 to check peripheral perfusion, while the difference was only about ten seconds.

TABLE Measured parameters

	Dolphin 2100	*Nellcor N-595*	*Masimo SET*
Time from 'power on' to acquire the pulse wave (sec)	9.9 ± 0.6	18.3 ± 0.6*	11.2 ± 0.3*,†
Time from 'power on' to acquire the SpO_2 (sec)	14.9 ± 0.3	21.1 ± 0.3*	14.2 ± 0.6*,†
Time from application of air tourniquet to loss of pulse wave (sec)	4.3 ± 0.2	3.4 ± 0.2*	5.6 ± 0.6*,†
Time from application of air tourniquet to loss of SpO_2 (sec)	21.8 ± 4.0	31.8 ± 1.6*	32.2 ± 1.8*
Time from release of tourniquet to acquire the pulse wave (sec)	4.4 ± 0.3	2.3 ± 0.1*	11.1 ± 0.4*†
Time from release of tourniquet to acquire SpO_2 (sec)	10.3 ± 0.2	4.6 ± 0.3*	14.4 ± 0.2*†

SpO_2 = oxygen saturation. *$P < 0.05$ *vs* Dolphin 2100; †$P < 0.05$ *vs* Nellcor N-595.

The Masimo SET might be more resistant than other monitors to the altered perfusion induced by a tourniquet. However, the Nellcor N-595 responded faster than the others when perfusion returned, and the Masimo SET was the slowest to recover. Application of tourniquet pressure at 250 mmHg might induce complete occlusion of blood flow rather than hypoperfusion in patients with normal blood pressure. Therefore, it might be possible that the response to loss of blood flow and to reflow was the slowest in the Masimo SET, which enabled the Masimo SET to show the pulse wave and SpO_2 longer than the other monitors, even when blood flow was occluded. This does not imply that the Masimo SET could detect the pulse wave and SpO_2 better than the other two systems at a reduced state of perfusion. Different blood pressures might influence the effects of the tourniquet. Although blood pressure was not measured in the present study, volunteers were young without hypertension, and each device was repeated for each subject. Therefore, the effects of blood pressure should be small.

Cooling the hand to 27°C, which was the lower limit in awake volunteers, had no effect on detecting pulse wave and SpO_2 in each monitor tested. However, it was unclear how the perfusion decreased at 27°C, though fingers were cyanosed. Methods using a tourniquet or cooling might be different from clinical situations with hypoperfusion, such as hypovolemia, deep anesthesia or shock secondary to sepsis etc., because humoral or neural responses might also bear an influence in such clinical situations.

There are several studies comparing the Masimo SET with conventional pulse oximeters. Using the cooling environment and tapping and rubbing motions, the Masimo SET performed significantly better during motion and hypoperfusion than the other pulse oximeters (Nellcor N-395, Tyco Healthcare, Pleasanton, CA, USA; Datex-Ohmeda AS/3, Datex-Ohmeda, Madison, WI, USA; Marquette 8000, GE Healthcare IT, Milwaukee, WI, USA).[4] In a study comparing the Masimo SET, Nellcor N-395, N-20PA, and D-25, time to loss of signal during blood pressure measurement by cuff was longer in the Masimo SET.[3] The Masimo SET and the Nellcor N-395 showed shorter times to recover than the other monitor types.[3] These studies suggest that the Masimo SET could offer advantages over conventional pulse oximeters. However, there have been no studies comparing the Masimo SET with other pulse oximeters using the new technologies.

Conventional pulse oximetry derives SpO_2 from the ratios of emitted *vs* transmitted light (Lambert-Beer's law), whereas the Masimo SET utilizes a patented discrete saturation transform algorithm to process the SpO_2.[2] The Masimo SET calculates SpO_2 without first referencing the pulse rate, whereas recognition of a stable pulse is prerequisite to conventional oximeters. Therefore, response time was faster with the Masimo SET than the conventional oximeters. The Masimo SET pulse rate and SpO_2 algorithms are so robust that they capture more true bradycardiac and hypoxemic events than conventional pulse oximeters during both motion and hypoperfusion.[5] The Nellcor N-595 has a digital tip in the sensor (OxiMax™, Tyco Healthcare, Pleasanton, CA, USA).[6] Each sensor of the OxiMax™ contains all the calibration and operating characteristics for that individual sensor. It allows an information exchange between the sensor and the monitor, improving monitoring performance.[6] Therefore, the Nellcor N-595 had a faster response than the Masimo SET. The Dolphin 2100 uses oximetry noise elimination (ONE™, Dolphin Medical, Hawthorne, CA, USA) technology, in which light signals are digitalized in the sensor. The different responses at hypoperfusion or occlusion of blood flow of these three monitors could not be related to the differences in technologies, due to lack of basic studies and details from the manufacturers. To better discriminate the clinical differences of these pulse oximeters, further studies using quantitative motion, hypoperfusion, and deeper cooling should be performed.

In conclusion, for the monitors tested, the Masimo SET was the slowest to respond to changes of perfusion, and the Nellcor N-595 responded the fastest. The Nellcor N-595 was the slowest to show SpO_2 and pulse wave at 'power on'.

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