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Comparability of pulse oximeters used in sleep medicine for the screening of OSA

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Abstract

Obstructive sleep apnea syndrome (OSA) is a frequent clinical picture. It is characterized by repetitive respiratory arrest with a consecutive decrease in arterial oxygen saturation (SaO_2). In clinical practice, the number of desaturations per hour, oxygen desaturation index (ODI), is used as an important diagnostic criterion. Medical literature, however, mentions different threshold values that are defined as pathological. By means of systematic comparative measurements, the study presented here will examine to what extent the diagnosis and the quantification of OSA severity are affected by the device-specific measurement technique, thus impacting the predictive value of nighttime pulse oximetry in outpatient OSA screening. Different pulse oximeters commonly used in clinical practice were analyzed comparatively regarding technical parameters, temporal dynamics and the reproducibility of measuring results. The measurements were executed simultaneously and time synchronized in a reference group of five test subjects (four males, one female, average age 33.0 ± 9.4 years), in a group of five patients (all males, average age 51.8 ± 18.4 years) and using a simulator (pulse oximeter simulator index 2). All devices underestimate the simulator's predetermined oxygen desaturation of 10%. The dispersion of values is high. The device-specific characteristics have a significant influence on the collected data. The fundamental weakness of the systems lies in the reproducibility of measuring results (this only seems adequate at a signal resolution in steps of 0.1%) as well as the differing temporal dynamics. In the synchronous use of different

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systems on patients for the purpose of a direct comparison of devices, the dispersion of values is serious, reaching a fluctuation range of up to factor 1.42. In measuring dynamic events (apneas), different pulse oximeters do not record identical values. This is due to the different internal signal processing of the devices. Without prior knowledge of the pulse oximeter used and the chosen device settings, meaningful interpretation of the measured desaturations is, therefore, ambiguous. Accordingly, different devices require different threshold values in determining the ODI. Standardized technical parameters and the standardization of signal processing are imperative for outpatient screening of sleep-related breathing disorders (SRBD) via pulse oximetry.

Keywords: sleep apnea screening, pulse oximetry, reproducibility, signal processing

(Some figures in this article are in colour only in the electronic version)

1. Introduction

Obstructive sleep apnea syndrome (OSA) is a frequent clinical picture. About 4–6% of the population in Western industrial countries (Young *et al* 2002, Punjabi 2008, Ram *et al* 2010) suffer from it. Episodes with complete or partial disruption of the respiratory flow lead to a decrease in oxygen saturation (SaO_2), which seriously affects a person's health. Among others, this applies to cardiovascular and cerebrovascular diseases, such as diabetes, coronary heart disease (CHD), stroke and hypertension (Peppard *et al* 2000, Kato *et al* 2009, Schulz *et al* 2001, 2006, Ip *et al* 2002, Podszus *et al* 2009). Therefore, early detection is important.

Because inpatient polysomnography (PSG)—the gold standard in the diagnosis of OSA—is expensive and time consuming, outpatient sleep apnea screening tries to collect substantial diagnostic information from a few signals (Ayas *et al* 2003, Chesson *et al* 2003).

In addition to the respiratory flow with thoracic and abdominal respiratory effort, cardiorespiratory sleep monitoring also records snoring signals, body position and oxygen saturation (SaO_2). The number of desaturations per hour—oxygen desaturation index (ODI)—is an important diagnostic criterion. In comparison to PSG, the nighttime pulse oximetry has a high predictive value regarding the OSA severity (Whitelaw *et al* 2005, Magalang *et al* 2003, Kirk *et al* 2003). In some countries, such as the United States, Australia and Sweden, pulse oximetry is accepted as the sole diagnostic evaluation criterion. With regard to single-channel measurement, the 'Apnea' task group of the German Society for Sleep Research and Sleep Medicine (DGSM) has stated '... aside from six-channel recording devices, only pulse oximetry, a vital parameter, has so far delivered scientific proof, that one is able to attain a tentative diagnosis that requires further evaluation at a sleep laboratory'. (Statement of the 'Apnea' task group of the DGSM 2006.)

The medical literature uses different threshold values that are defined as pathological. These threshold values range from a 3% to 5% decrease in SaO_2 (Chiner *et al* 1999, Schäfer 1996, Penzel *et al* 1993, for overview see Flemons *et al* (2003)). The guidelines do not define threshold values. In cases of hypopneas, the AASM-Scoring-Manual defines it as a 3% or 4% decrease in SaO_2 (AASM: Iber *et al* 2007).

The fact that no standardized threshold value could so far be defined is mainly due to a lack of comparability of the different pulse oximeters.

In clinical practice, pulse oximeters are calibrated by means of statical measurements. The required accuracy is attained through the internal signal processing of the device, which generally includes information on several measurements (averaging). Because quick alterations of the signal as well as sudden peak and minimum values are computationally eliminated (elimination of artifacts), the signal processing significantly affects the response to quick alterations of the input parameters, as is frequently observed in sleep medicine. Numerous studies (Gehring *et al* 2002, Davila *et al* 2002, 2003, Senn *et al* 2005 and Zafar *et al* 2005) did not only observe this correlation, but have also described the effect on the recorded AHI (numbers of detected apneas per hour). Davila, therefore, concludes that additional information about the kind of device and the applied device settings is essential (Davila *et al* 2003). However, all of these studies have in common that these effects were only examined in measurements in patients. Here, however, the true signal trace of the oxygen saturation remained unknown because these values were measured only by the devices in use. Therefore, a quantification of the effects of different signal processing was impossible.

While the current guidelines of professional associations (AASM 2007 and DGSM-S3 2009) state minimum specifications for the sample rate of pulse oximeters used in sleep medicine, they do not set a standard with regard to measuring accuracy in cases of rapid alterations. In order to present quantifiable conclusions regarding the used pulse oximeters' adequacy for the OSA diagnostics, this study performed systematic comparative measurements. These findings are intended to contribute to improvement of the qualified early detection of OSA.

2. Method

Five systems widely used in clinical practice for measuring SaO_2 were examined. Mobile wrist pulse oximeters used for outpatient OSA screening as well as pulse oximeters used in PSG-measuring systems for OSA diagnostics (manufacturer, maximum sample rate, resolution, accuracy in the area of 70–100% SaO_2) were selected.

(A) *Model 3100 WristOx* (Nonin, Plymouth, MN, USA: 1 Hz, 1%, ±2%);
(B) *PSG system Somnolab* (Weinmann, Hamburg, Germany: 16 Hz, 1%);
(C) *Model Pulsox 300i* (Konica Minolta Sensing Europe, Nieuwegein, The Netherlands: 1 Hz, 0.1%, ±2%);
(D) PSG system (Compumedics, Singen, Germany: 1 Hz, 1%, ±2%);
(E) *Model ChipOx* (MCC Gesellschaft für Diagnosesysteme in Medizin und Technik mbH & Co. KG, Karlsruhe, Germany: 100 Hz, 1%, ±2%). This device allows for the adjustment of the measuring dynamics. The user can choose between sensitive, normal and stable mode.

2.1. Measurements with the simulator

In order to compare the technical parameters as well as the temporal dynamics of the pulse oximeters, additional measurements were executed with the pulse oximeter simulator index 2 (Fluke, figure 1). The simulator allows the reproducible generation of temporally adjustable test signals of oxygen saturation. Within one test sequence, ten different SaO_2-values with a definable time interval can be initiated. That way, not only rapid alterations, but also typical apnea time courses (sawtooth) can be generated and stored.

By examining the step response of a simulated abrupt saturation decrease from 98% to 93%, the temporal dynamics of different devices is compared. Furthermore, the reproducibility

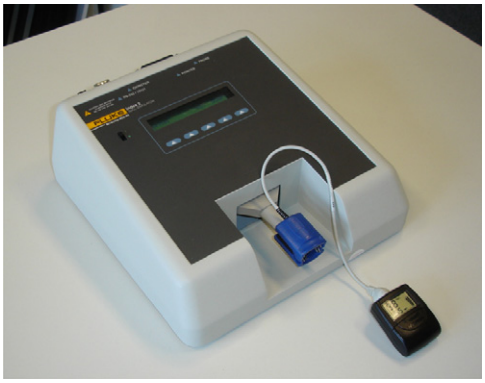

Figure 1. Test set-up of measurements with the pulse oximeter simulator index 2 (Fluke).

of step response to an abrupt 5% saturation decrease is examined. Subsequently, devices and sensors were compared with regard to simulated sawtooth-shaped apnea of 10% saturation decrease.

2.2. Measurements in test subjects and patients

Furthermore, a reference group of five test subjects (four males, one female, average age 33.0 ± 9.4 years) and five patients (all males, average age 51.8 ± 18.4 years) was examined. The selection of test subjects was carried out considering the following in- and exclusion criteria. In compliance with the Helsinki declaration, the written consent of the patients and the test subjects was obtained after they had been informed.

The inclusion criteria demanded the written consent to the examination as well as the patients' acceptance of wearing a pulse oximeter at night in addition to the PSG feed. Exclusion criteria for the participation in this study were symptoms of dementia, severe neurological conditions (Parkinson's disease), severe endocrinal disorders (hypo- and hyperthyreosis) and lung diseases (COPD).

In the examination of five test subjects, endexspiratory apneas with a defined duration (10 s, 15 s, 20 s, 25 s, 30 s as well as the maximum duration possible) were simultaneously recorded with different systems under laboratory conditions. In order to eliminate side-to-side differences, the sensors of the individual measuring systems were all applied to the same hand (figure 2). The sensors' allocation to the different fingers regarding individual measurements was randomized. To avoid faulty saturation values due to the influence of external light sources (i.e. the light of neighboring sensors), the sensors were optically shielded.

In order to synchronize the time of the measuring systems that were used, the PC system time was set via a radio-controlled clock before the start of each examination. This PC system time was then transferred directly onto those pulse oximeters with an internal data recording capability (device 1 and device 3) via its device specific software.

Furthermore, pulse oximetric measurements (device 1) were performed at a sleep laboratory in parallel to nighttime polysomnography (device 5). In order to examine the obtained SaO_2-values' dependence on the device's signal processing, device 5 was operated in sensitive and stable mode (the sensitive and stable mode differ in averaging time.)

The data evaluation was carried out using device specific software, as well as Excel and MATLAB. Because the examinations are based on a relatively small patient group, a statistical analysis was waived.

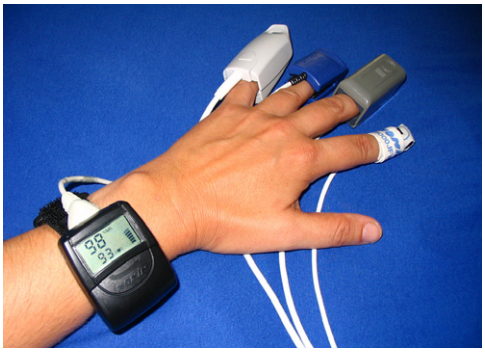

Figure 2. Measuring set-up of comparative measurements in test subjects.

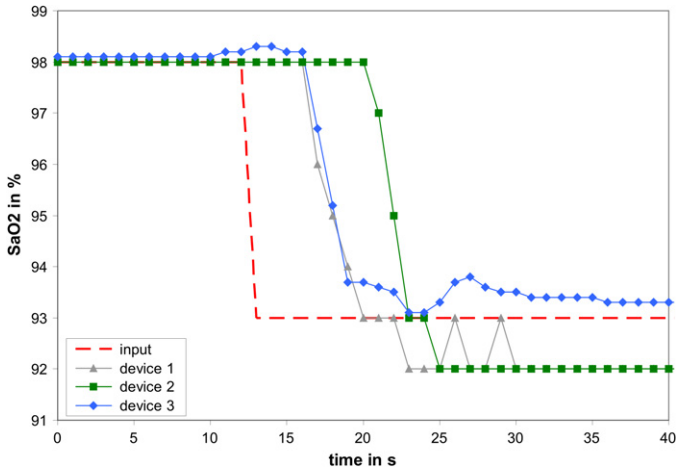

Figure 3. Step response of different devices. The simulated saturation decrease of 5% SaO_2 corresponds to a typical desaturation of clinically relevant apneas.

3. Results

3.1. Examination of the time response: step response

Figure 3 shows the recorded response, measured with devices 1, 2 and 3, following an abrupt saturation decrease. The step responses display different kinds of low pass characteristics, responsible for the differing results when measuring dynamic signals.

In the measuring signal, the desaturation becomes visible with a time delay compared to the input signal (step function). In this case, device 2 requires the longest response time. While device 3 exhibits a linear decrease of SaO_2-values after the initial step, device 1 shows an exponential time response in this regard. Based on system theory, this step response was described in Eilers *et al* (2009). The observed deviation of SaO_2-values from the reference value (input signal) after the step is within the tolerance range specified by the manufacturer.

3.2. Examinations of reproducibility (simulator)

Figure 4 indicates the reproducibility of the measuring results in the case of a stepwise change in oxygen saturation of 5% SaO_2. Here, the desaturations as well as the stepwise

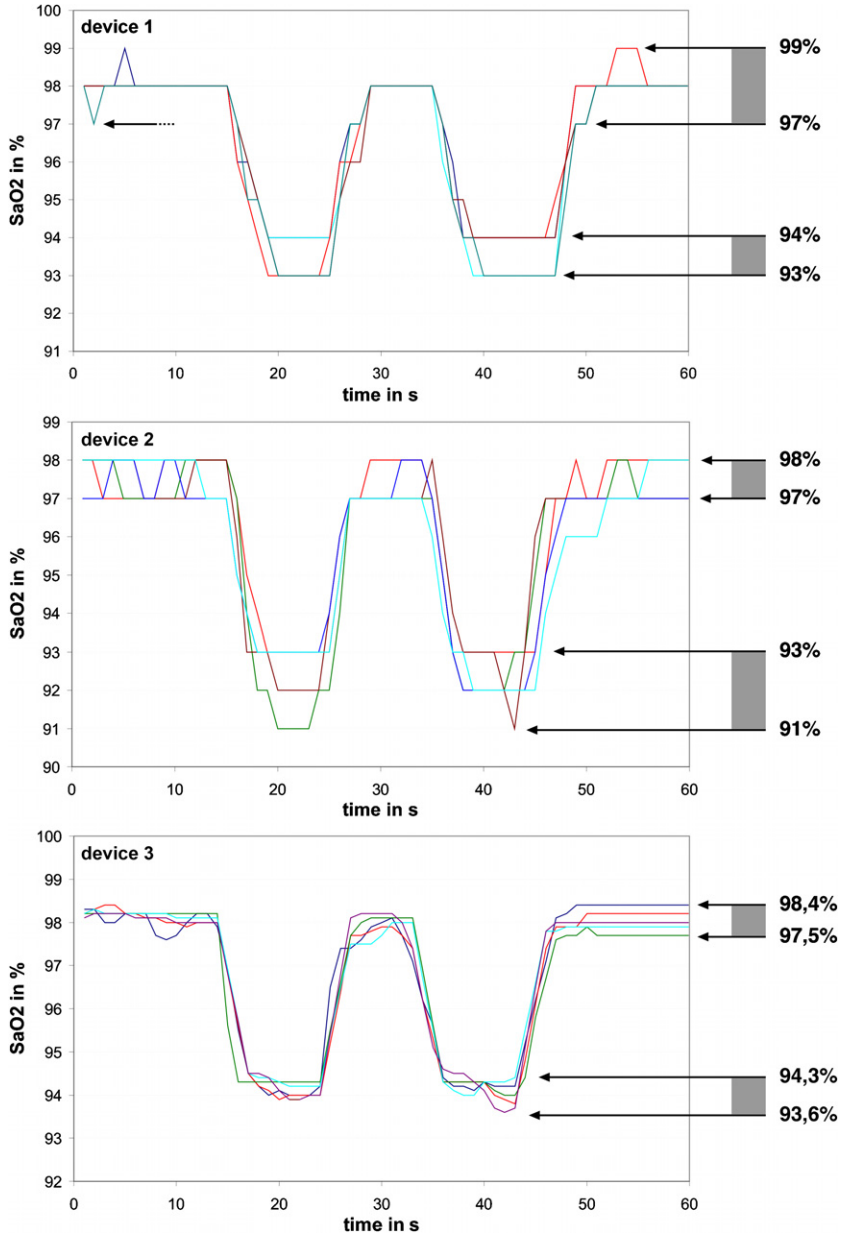

Figure 4. Reproducibility of SaO_2 steps with a desaturation of 5%. For device 1 (top) the measured values range from 97 to 99% SaO_2 for the upper as well as from 93 to 94% SaO_2 for the lower plateau of the step. For device 2 (middle) the values range from 97 to 98% SaO_2 (upper plateau) and from 91 to 93% SaO_2 (lower plateau). For device 3 (bottom) the values range from 97.5 to 98.4% SaO_2 (upper plateau) and from 93.6 to 94.3% SaO_2 (lower plateau).

increase of saturation values were examined. The deviations of individual measurements with one and the same device are within the precision range specified by the manufacturers. The measurements with device 3 are closest to each other due to the better resolution of the device. The reproducibility of measurements with device 1 was better than with device 2.

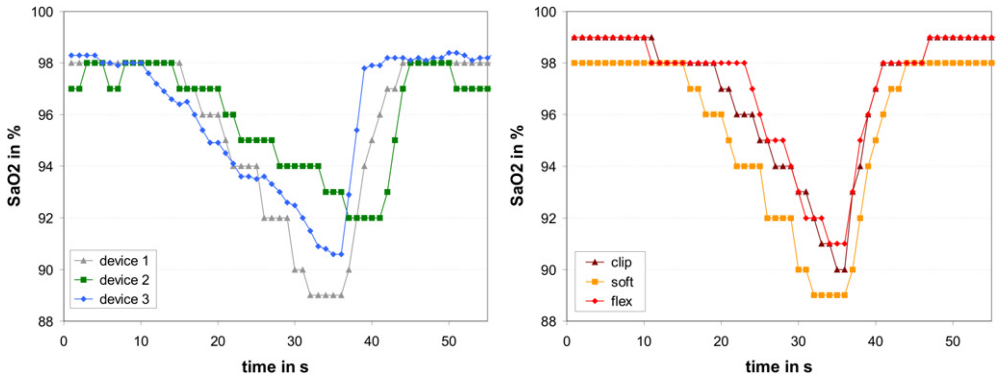

Figure 5. Comparison of different devices (left) as well as different sensors (right) in simulated apneas with 10% desaturation (SaO_2 decrease from 99% to 89%).

3.3. Simulation of apneas with the simulator

Figure 5 illustrates the results of a device and sensor comparison in simulated sawtooth apneas.

It is noticeable that device 2 shows the worst temporal dynamics, while also recording the lowest desaturation value. All devices underestimate the predetermined desaturation of 10%. With a recorded desaturation of 9%, device 1 is within the tolerance range. Devices 2 and 3 only detect a desaturation of 6% and 7.7% SaO_2 respectively.

The flex sensor's recorded desaturation is 1% lower than the soft and clamp sensor's readings. This, however, falls within the range of reproducibility of device 1 as well as within the tolerance range specified by the manufacturers.

3.4. Comparison of different devices in patients under laboratory conditions

With regard to simulated apneas, the different devices' results were validated in measurements in test subjects. Figure 6 exemplifies the course of the oxygen saturation, which was measured with three different devices during endexspiratory apneas. With regard to all apneas, device 5 (sensitive mode) detected a higher desaturation level than device 1. In this test subject's case, the recorded desaturations in 10–15 s apneas differed by 1–2% (not illustrated), in 20–30 s apneas by an average of 2% and in 60 s apneas by 4%.

Regarding apneas 2, 3, 4 and 7, the minima of oxygen saturation displayed by device 2 are lower than the ones shown by device 5. In apnea 10, the minimum saturation shown by device 2 (with a value of 89%) is well above the minimum saturation recorded by device 1 (85%) and device 5 (81%). In apneas 2, 3 and 10, this deviation can be attributed to a reduced signal intensity in device 2 (figure 6, bottom). Therefore, further evaluation included only oximetry data with a signal quality of 100%.

Figure 7 shows a recording of a test subject's apnea (duration of 53 s), which, after a single deep breath, is followed by a second apnea (duration 42 s). In comparison to the breathing effort, all three devices show a time delay of 18–21 s with regard to the oxygen saturation. Due to its low averaging time (sensitive mode), device 5 exhibits the best temporal dynamics. Therefore, the oxygen saturation increases more rapidly during the 'intermediate breathing', almost reaching the initial value. However, the other two devices do not reach the initial value.

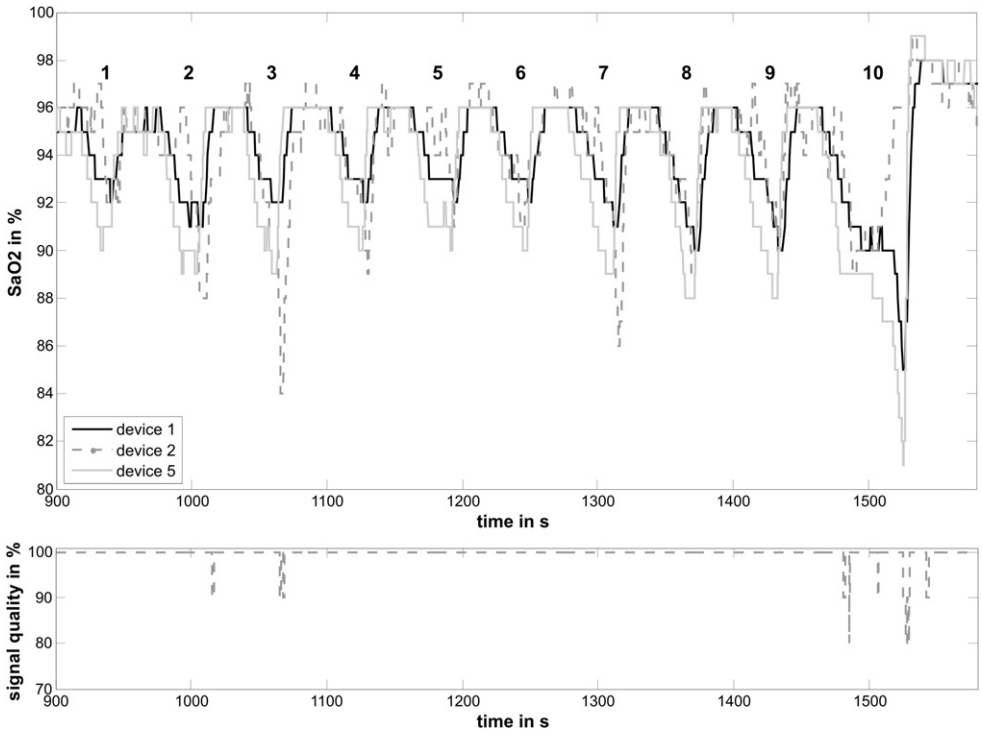

Figure 6. Representative course of oxygen saturation in apneas of a defined duration (apnea 1–3: 20 s, 4–6: 25 s, 7–9: 30 s, 10: 60 s)—comparative measurements with three devices (top). Signal quality of device 2 (bottom). The signal quality of device 5, which was applied in sensitive mode, amounted to 100% in all measurements.

As a consequence, the detected desaturation level during the second apnea is too low. Once again in this investigation, device 2 showed the worst temporal dynamics.

3.5. Comparison of desaturations measured with different devices (test subjects/patients)

In the illustrated comparison between different systems and device 1 (figure 8), a linear correlation can be observed. Because no desaturation is expected in the case of stable breathing, the regression line runs through the origin. It must, however, be observed that the recorded slopes of the regression lines are only valid for certain areas of the desaturation.

The slope of the regression line in figure 8(a) is 1.42, i.e. device 5, on average, displays a 1.42-fold desaturation compared to device 1. In cases in which device 5 (in sensitive mode) would record a desaturation of 4%, device 1 only displays desaturations of 2 or 3% in apneas.

The slope of the regression line in figures 8(b)–(d) indicates a value of almost 1, so that on average all devices showed the same desaturation in apneas.

The biggest spread of values around the regression line can be found in the comparison of device 1 and device 2 (figure 8(b)): whereas device 1 only indicates a desaturation of 4% for an apnea, device 2 shows a desaturation of 3–8%.

3.6. The desaturation's dependence on the signal processing

The recorded desaturation's dependence on the signal processing is exemplified in figure 9. With regard to the illustrated measurement, device 5 was initially applied in sensitive mode, and

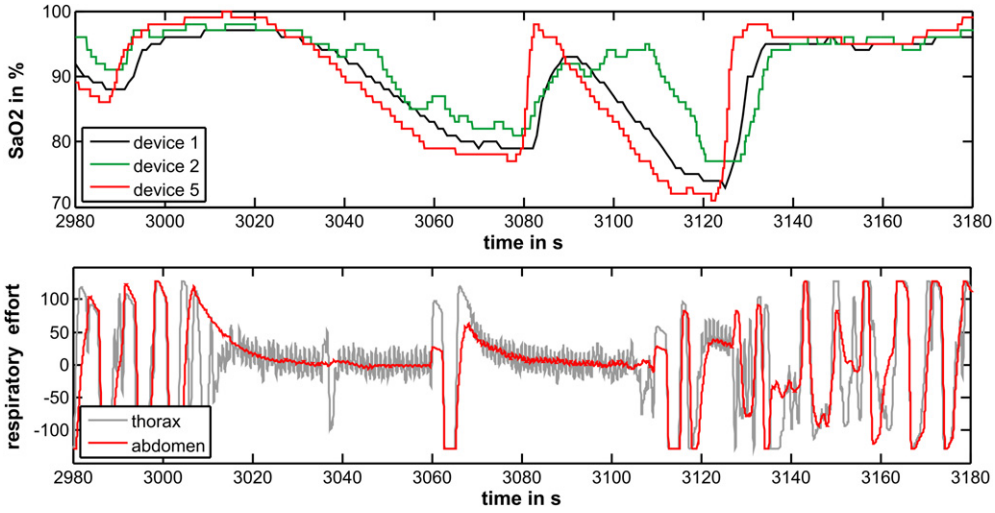

Figure 7. Time course of oxygen saturation in immediately successive apneas with one intermediate breathing. Comparative measurement of different devices (top). Breathing effort in thoracic and abdominal area as temporal reference (bottom).

then in stable mode. In sensitive mode device 5 displayed significantly higher desaturations than reference device 1 (average desaturation 22.3% for device 5 and 15.3% for device 1). In stable mode, however, the desaturations were only 2% above the reference values.

Figure 10 illustrates a direct comparison of recorded desaturations of devices 1 and 5 regarding endexspiratory apneas with a duration between 30 and 95 s. Due to its piecewise linearity, the regression lines, in this case, may not run through the origin. As expected, the slope of the regression line for device 5 in stable mode is smaller, which is due to this mode's longer averaging time.

4. Discussion

In clinical practice, the diagnosis and the quantification of the OSA severity follow technically recorded parameters. These 'absolute' values, however, need to be reviewed critically because the results significantly depend on the used measurement technique. Therefore, in addition to the definition of pathological threshold values, the professional associations' guidelines should also include the technical specifications for the devices in order to ensure the comparability of measuring results, and to reach a valid definition of a threshold value.

Besides the ODI, additional evaluation criteria, which do not only depend on the desaturation amplitude, should be considered in the OSA screening via nighttime pulse oximetry. Promising variability parameters include the Δ-index (Pépin *et al* 1991, Flemons *et al* 2003, Schultheiß *et al* 2007), spectral range parameters (Zammarón *et al* 2003, Schultheiß *et al* 2008), parameters of nonlinear dynamics (central tendency measure) (Álvarez *et al* 2007, Schmittendorf *et al* 2009) as well as the approximate entropy (Hornero *et al* 2005, 2007, Schmidt *et al* 2008).

This study identifies the following three main problems: temporal dynamics, reproducibility of measuring results and the spread of results in the synchronous use of different systems.

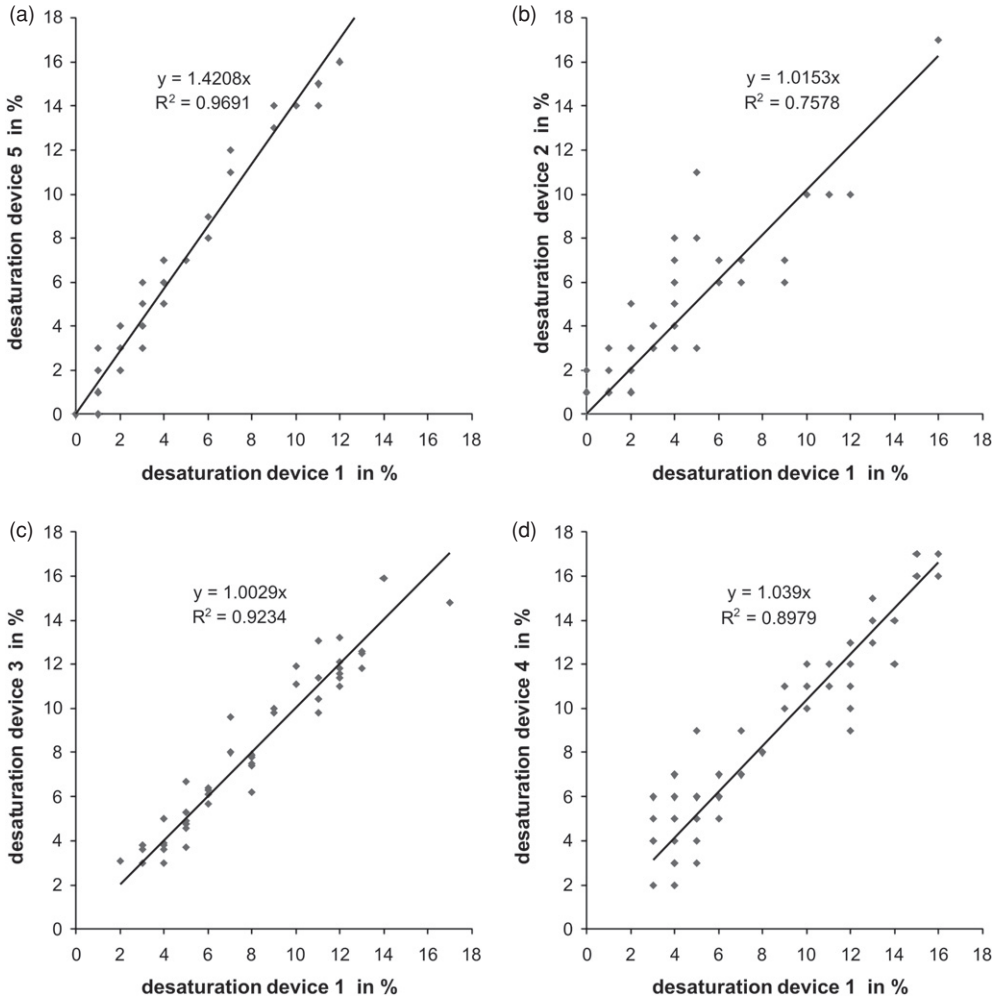

Figure 8. Comparison of measured desaturation, recorded with different devices; in each case device 1 is compared to a different system. (a)–(c) Measurements in test subjects, 53 apneas. The apnea duration is comparable to the duration of apneas in OSA patients. Device 5 was applied in sensitive mode. (d) Measurements in patients (patients without cardiac arrhythmia), 72 apneas.

4.1. Temporal dynamics

The temporal dynamics of the measuring devices is determined by the internal signal processing of the device. Thus, device 5 in sensitive mode reached the best temporal dynamics. A good temporal dynamics is required because in clinical practice, apneas can manifest in short repetitive intervals (typically 30–70 s) (Zammarón *et al* 2003). When using amplitude criteria in OSA diagnostics (as used in ODI definition), it must be ensured that the SaO_2 maximum value is reached before the onset of the next apnea. The time delay observed in the step response is clinically irrelevant. The transient response observed in device 3 is largely suppressed in the other devices (devices 1 and 2) due to a lower resolution of 1% SaO_2. The simulation of apneas shows that different pulse oximeters present them differently. Some of the devices tested in our study guarantee quite sufficient temporal dynamics. This means that in the case

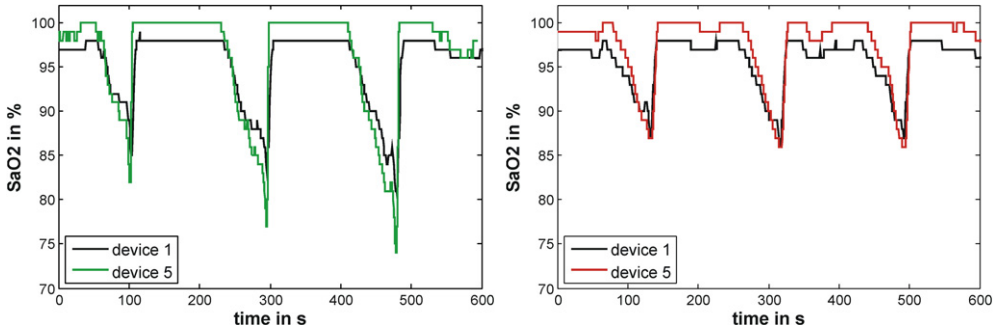

Figure 9. Time course of oxygen saturation in apneas of maximum duration. Device 5 was applied in sensitive mode (left) and stable mode (right).

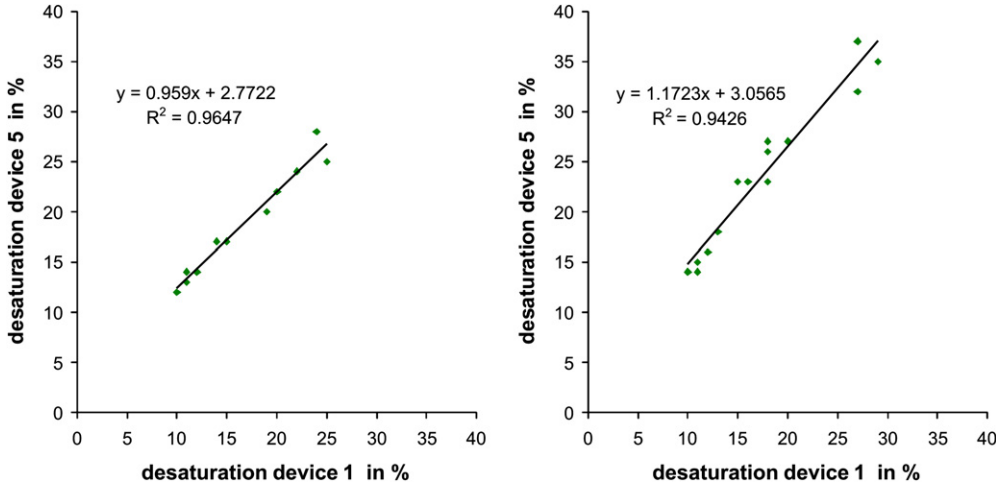

Figure 10. Comparison of measured desaturations with different device settings of device 5: stable mode (left) and sensitive mode (right). In each case, device 1 serves as a reference. Measurements in test subjects, 11 apneas with a duration of 30–95 s.

of repetitive apneas the extreme values (minima and maxima in the SaO_2 time course) are reached and the desaturation amplitude is not underestimated.

4.2. Reproducibility of measuring results

The reproducibility tests have shown that the spread of individual measurements falls within the tolerance range of $\pm 2\%$ SaO_2 specified by the manufacturers. Overall, device 3 shows the best reproducibility, which could be caused by a signal resolution in steps of 0.1%. Compared to the amplitude of apnea events ($\geqslant 4\%$ SaO_2) a signal resolution of 0.1% SaO_2 appears to be generally recommendable.

4.3. Spread of results in the synchronous use of different systems

The comparison of devices shows that different pulse oximeters do not display identical values in synchronous measurements. Therefore, one needs to be aware which pulse oximeter is being used.

For instance, the desaturations recorded by device 5 in sensitive mode are 1.42 times higher compared to those recorded by device 1. Concerning the diagnostic importance of the oxygen desaturation, which is the exclusive criterion in determining the ODI, this fluctuation range is unacceptable. Accordingly, different devices may require different threshold values for determining the ODI.

Devices with an adjustable averaging time should always be set to the highest temporal dynamics.

5. Conclusion

In the synchronous measurements of dynamic events (apneas), different pulse oximeters do not record identical values. This is due to a difference in the internal signal processing of the devices. Therefore, without prior knowledge about the used pulse oximeter and the chosen device settings, a meaningful interpretation of the recorded desaturations is impossible.

Particularly in the clinical evaluation of the ODI this needs to be considered. Many studies use a threshold value of a 4% oxygen desaturation as the standard for diagnostic decision. Due to technical reasons and device-specific signal processing (artifact elimination, averaging time, etc) this threshold is not an absolute value and should always be replaced by a device-specific one.

Thus, the definition of the minimum technical specifications and the standardization of the signal processing are required. The AASM proposes a sample rate of 25 Hz with the averaging of three values (Iber *et al* 2007). Additionally, for the detection of short apneas a resolution of 0.1% seems desirable to us. For SRBD screening by pulse oximetry these technical parameters should become compulsory.

Due to the measuring inaccuracy of $\pm 2\%$ SaO_2, the diagnostic evaluation of borderline findings in OSA screening via nighttime pulse oximetry should include additional diagnostic criteria that do not depend on the absolute desaturation amplitude. In addition to further diagnostic criteria already mentioned in this study (variability parameters, spectral range parameters, parameters of nonlinear dynamics and approximate entropy (Pépin *et al* 1991, Flemons *et al* 2003, Schultheiß *et al* 2007, 2008, Zammarón *et al* 2003, Álvarez *et al* 2007, Schmittendorf *et al* 2009, Hornero *et al* 2005, 2007, Schmidt *et al* 2008)), additional anamnestic parameters (such as the patient's biometric data, description of discomfort and comorbidities) should be considered in the diagnosis and the quantification of OSA severity and the decision to initiate further differential diagnostic steps or treatment.

Nighttime pulse oximetry is a comprehensive screening method for the identification of patients with moderate to severe OSA, as determined by the ODI. The device-specific discrepancies demonstrated in our study are of considerable clinical importance. Especially in patients with frequent apneas of short duration, showing only minor desaturation of single-apnea events, this can lead to an incorrect diagnostic exclusion of patients requiring treatment.

The authors take into account that a possible limitation of the study may result from the small sample size of patients as well as oximetry devices.

Acknowledgments

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