TECHNIQUES AND PROCEDURES

Transcutaneous Measurement of Partial Pressure of Carbon Dioxide and Oxygen Saturation: Validation of the SenTec Monitor

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OBJECTIVE: To validate a monitor for transcutaneous measurement of oxygen saturation (SpO_2) and partial pressure of carbon dioxide ($TcPCO_2$).

PATIENTS AND METHODS: This observational study included 140 Caucasian nonsmokers without jaundice. Patients underwent forced spirometry, measurement of SpO_2 and $TcPCO_2$ with the SenTec monitor, and arterial blood gas analysis (readings with 2 devices) during the stabilization phase of the monitor. In the statistical analysis, values from the 2 devices for measuring arterial blood gases were compared by mean differences for $PaCO_2$ and oxygen saturation (SaO_2). The arithmetic mean of the 2 blood gas measurements was calculated and relations between them and the SpO_2 and $TcPCO_2$ were assessed by the Pearson correlation coefficient (*r*) and the intraclass correlation coefficient (ICC) as a measure of agreement. Bland-Altman analysis was used to test data dispersion.

RESULTS: Ten patients were excluded due to a systematic error in the gas calibrator. The mean (SD) time to stabilization of the monitor before reading was 13.9 (2.4) minutes. The forced expiratory volume in the first second was greater than 80% in 40 patients, between 60% and 79% in 23, between 40% and 59% in 30, and less than 40% in 37. The mean differences between arterial blood gas measurements were 0.28 (1.0) mm Hg for $PaCO_2$, –0.06% (0.86%) for SaO_2, and –0.9 (2.7) mm Hg for PaO_2. In the tests for correlation and agreement, *r* was 0.74 and ICC was 0.73 for SaO_2 and SpO_2; *r* was 0.92 and ICC was 0.92 for $PaCO_2$ and $TcPCO_2$. The subgroup analyses did not show any noteworthy differences. The Bland and Altman analysis showed no significant dispersion. It was observed that the SenTec monitor underestimated oxygen saturation values by around 1% with respect to SaO_2 and overestimated carbon dioxide pressure by 1 mm Hg with respect to $PaCO_2$ values.

CONCLUSIONS: The stabilization time recommended for the SenTec monitor before taking a reading is 20 minutes. The overestimates and underestimates by the monitor are not clinically relevant. Finally, the values for SpO_2 and $TcPCO_2$ measured by the validated monitor are reliable.

Key words: *Carbon dioxide partial pressure determination, transcutaneous. Severinghaus type sensor. Pulse oximetry.*

Transcutaneous Measurement of Partial Pressure of Carbon Dioxide and Oxygen Saturation: Validation of the SenTec Monitor

OBJETIVO: Validar un monitor que mide la saturación de oxígeno y la presión parcial de anhídrido carbónico por vía transcutánea (SpO_2 y $PtcCO_2$).

PACIENTES Y MÉTODOS: Se ha realizado un estudio observacional en el que se incluyó a 140 pacientes de raza caucásica, no fumadores y sin ictericia. Se les realizó: espirometría forzada, medición de la SpO_2 y $PtcCO_2$ mediante el monitor SenTec y gasometría arterial (lectura en 2 gasómetros) durante la fase de estabilización del monitor. En la evaluación estadística se compararon los valores de las 2 mediciones de gasometría arterial mediante media de diferencias para la presión arterial de anhídrido carbónico ($PaCO_2$) y la saturación de oxígeno (SaO_2). Se calculó la media aritmética entre las 2 gasometrías, además del coeficiente de correlación de Pearson (r) y el coeficiente de correlación intraclase (CCI) entre SaO_2 y SpO_2 y $PaCO_2$ y $PtcCO_2$ como medida de concordancia. Se aplicó el análisis de Bland y Altman para el estudio de la dispersión de datos.

RESULTADOS: Se rechazó a 10 pacientes debido a un error sistemático por problemas del gas calibrador. El tiempo medio (± desviación estándar) de estabilización del monitor antes de lectura fue de 13,9 ± 2,4 min. El volumen espiratorio forzado en el primer segundo fue superior al 80% en 40 pacientes; se situó entre el 60 y el 79% en 23; entre el 40 y el 59% en 30, y fue menor del 40% en 37. La media de diferencias entre las gasometrías arteriales fue: para la $PaCO_2$, 0,28 ± 1,0 mmHg; para la SaO_2, –0,06 ± 0,86%, y para la presión arterial de oxígeno, –0,9 ± 2,7 mmHg. En cuanto a la correlación y concordancia, los resultados fueron los siguientes: para la SaO_2 y SpO_2, r = 0,74 y CCI = 0,73; para la $PaCO_2$ y $PtcCO_2$, r = 0,92 y CCI = 0,92. El análisis por subgrupos no mostró diferencias destacables. El análisis de Bland y Altman no demostró dispersión significativa de datos. Se observó que el monitor SenTec infravaloró los valores de SaO_2 alrededor del 1% y sobrevaloró los de $PaCO_2$ en 1 mmHg.

CONCLUSIONES: El tiempo de estabilización aconsejable del monitor SenTec antes de realizar una lectura es de 20 min. Las sobrevaloraciones e infravaloraciones del monitor carecen de traducción clínica. Por último, los valores obtenidos de SpO_2 y $PtcCO_2$ del monitor validado son fiables.

Palabras clave: *$PaCO_2$ transcutáneo. Sensor tipo Severinghaus. Pulsioxímetro.*

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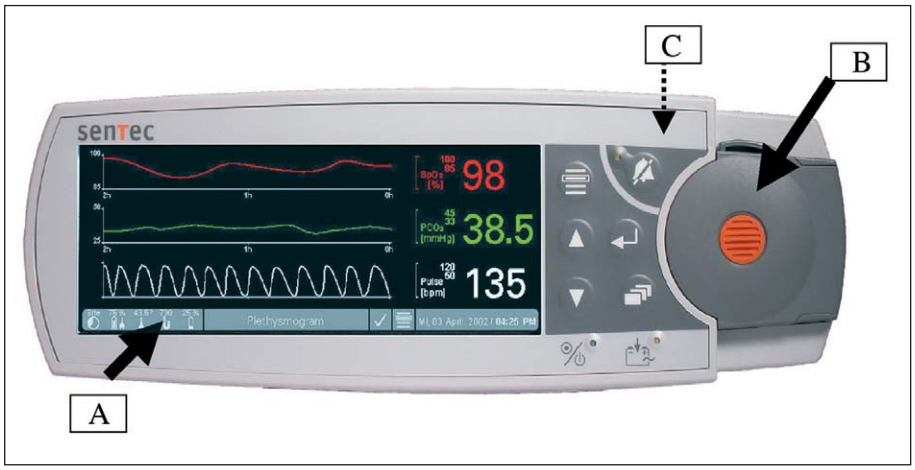

Figure 1. V-sign™ monitor (SenTec, Therwil, Switzerland). *A:* Monitor screen displaying, from top to bottom, oxygen saturation, transcutaneous partial pressure of carbon dioxide, and heart rate. *B:* Port housing the V-Sign™ sensor membrane, which should be changed frequently. *C:* The calibration gas cylinder is subsequently put in place.

Introduction

In the 1950s, reports of blindness caused by oxygen therapy administered to premature babies stimulated interest in the development of noninvasive techniques for measuring PaO_2. Later, clinicians became interested in measuring $PaCO_2$ as well. The interest in noninvasive measurement of both $PaCO_2$ and PaO_2 subsided in view of the technical and practical problems associated with the measuring devices used (Table 1) and the introduction in 1985 of pulse oximetry, which has proved effective[1,2] for noninvasive assessment of oxygenation during sleep[3] and exercise.[4,5] Pulse oximetry cannot, however, provide information on $PaCO_2$, that is, on the patient's ventilation. Therefore, it is important to have a technique available for noninvasive monitoring of $PaCO_2$. Moreover, continuous monitoring, and not just measurement at discrete times, is also desirable. Some findings already point to the reliability of devices for transcutaneous measurement of oxygen saturation (SpO_2) and $PaCO_2$ ($TcPCO_2$).[6-9]

The aim of this study was to assess the reliability of a monitor of SpO_2 and $TcPCO_2$ in patients at rest with mild, moderate, and severe chronic obstructive pulmonary disease, and in healthy controls at rest, all of whom were breathing room air.

TABLE 1
Drawbacks of Traditional Devices for Transcutaneous Measurement of Carbon Dioxide

Burns resulting from the high temperature of the electrodes
Skin abrasion resulting from excessive friction of the electrodes
Unreliable readings in patients with acidosis
Long times for calibration and stabilization
Need to change application site of the electrodes every 2-4 h

TABLE 2
Measurement Procedure for the V-Sign™ Monitor*

Permanent connection of the device to the electricity grid
Calibration is done automatically before each measurement
Check level of calibration gas
Clean the earlobe of the patient with gauze soaked in alcohol
Place a drop of conducting gel on the surface of the sensor membrane
Place the clip with the sensor on the patient's earlobe
Stabilization of the partial pressure of carbon dioxide and oxygen saturation

*SenTec Inc, Therwil, Switzerland.

Patients and Methods

Patients

A consecutive Caucasian population of nonsmokers free of jaundice was studied. All patients had been referred to the respiratory function testing clinic of our hospital for forced spirometry and arterial blood gas analysis. The minimum number of patients to be recruited was 120 to yield 4 categories of 30 patients each.

Methods

The study was observational. All patients underwent forced spirometry (System 1070, Series 2E/1085, MedGraphics, St. Paul, MI, USA) on the same day of the study. Spirometry was carried out in accordance with the guidelines of the Spanish Society for Pulmonology and Thoracic Surgery (SEPAR).[10] Reference values were those published for a Mediterranean population.[11] SpO_2 and $TcPCO_2$ were then measured with the V-Sign™ combined monitor (SenTec Inc, Therwil, Switzerland). According to the manufacturer's specifications, the monitor weighs 2.5 kg (5.5 lbs) and measures 10.2×27.0×23.0 cm (4.00×10.63×9.06 inches). It is equipped with a disposable clip electrode that has to exert sufficient pressure on the earlobe for it to function properly. The monitor automatically calibrates itself every time the port door is closed (Figure 1). It is recommended to change the sensor membrane every 2 weeks because the electrolytes between the sensor and the membrane become depleted. Readings were taken according to the procedure described in Table 2 and Figure 1. The time from when the sensor was placed on the earlobe until the reading stabilized was defined as the stabilization time.

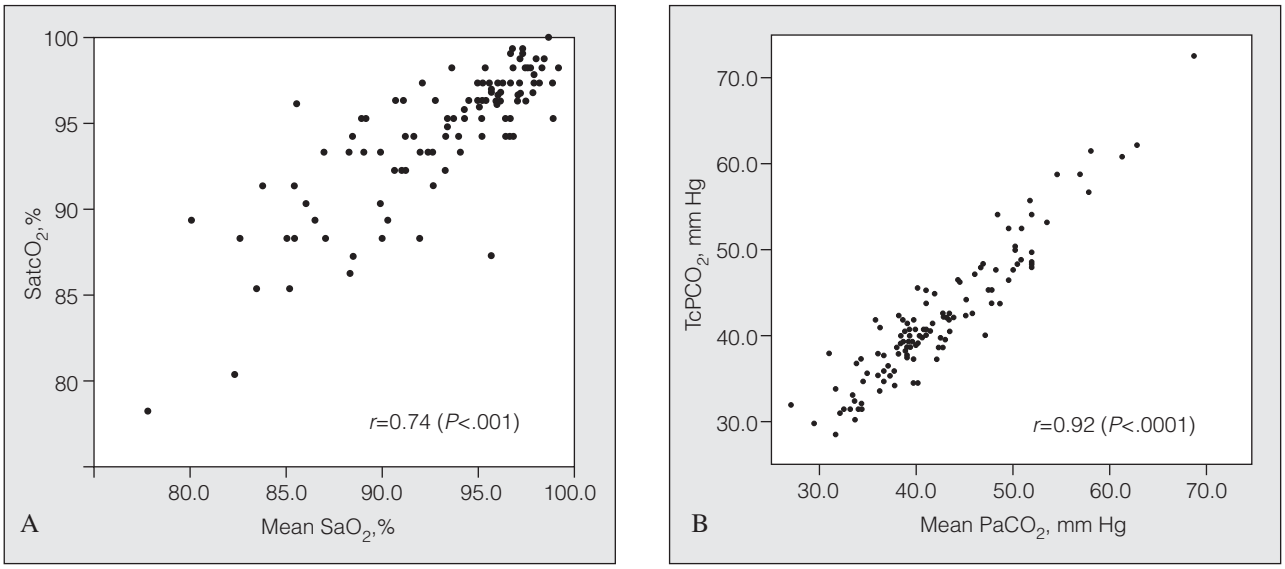

Figure 2. ***A:*** **Correlation between values for oxygen saturation obtained with the V-Sign™ monitor (SenTec Inc, Therwil, Switzerland) (SpO_2) and arterial blood gas analysis (SaO_2).** ***B:*** **Correlation between values for $PaCO_2$ obtained by arterial blood gas analysis and a transcutaneous measure obtained with the V-Sign™ monitor ($TcPCO_2$).**

During the stabilization period, arterial blood gas analysis was performed in accordance with SEPAR guidelines,[12] which include the use of subcutaneous anesthesia before puncture. The sample for arterial blood gas analysis was processed in 2 analyzers and hemoximeters, those belonging to the respiratory function testing laboratory (Radiometer ABL 500 series, Copenhagen, Denmark; Radiometer OSM3 hemoximeter) and immediately afterwards in those belonging to the intensive care unit (ICU) (Radiometer ABL 700 series; Radiometer OSM3 hemoximeter). Even though the 2 laboratories are on the same floor and close to one another, the blood samples were transported between the 2 sites on ice. At least 2 readings were taken with each analyzer for each blood sample. The optimal value was always taken (higher PaO_2 and lower $PaCO_2$) when the values differed by less than 1 mm Hg, otherwise a third reading was recorded.[13] The arithmetic mean of the readings from the 2 analyzers was calculated and the result was taken as the reference value from the arterial blood gas analysis. The body temperature of the patient was specified on analysis of the blood sample.

Statistical Analysis

Anthropometric, spirometric, and arterial blood gas data were expressed as means (SD). Arterial blood gas values processed in the respiratory function testing clinic were compared with those from the ICU by calculating the mean differences for $PaCO_2$ and oxygen saturation (SaO_2). The Pearson correlation coefficients (r) between $PaCO_2$ and SaO_2 and between $TcPCO_2$ and SpO_2 were determined. Finally, a concordance study was done by calculating the intraclass correlation coefficient (ICC) and with a Bland-Altman analysis. The study was approved by the ethics committee of our hospital.

Results

The study included 140 consecutive patients, although 10 patients with readings taken on 2 of the study days were excluded from the analysis because of a systematic error in the measurement due to low levels of calibrator gas. Therefore, 130 patients were analyzed. The mean time to take a reading, once the nurse considered that the monitor had stabilized, was 13.9 (2.4) minutes. Table 3 summarizes the patients' age and their anthropometric, spirometric, and arterial blood gas variables. No cases of elevated carboxyhemoglobin, indicative of recent smoking, were detected. The mean difference between the arterial blood gas values processed in the respiratory function testing clinic and the ICU was 0.28 (1.0) mm Hg for $PaCO_2$ and –0.06% (0.86%) for SaO_2.

The comparisons between SaO_2 and SpO_2 are presented in Table 4 for the entire study population (Figure 2A) and for patients grouped according to the severity of respiratory dysfunction. Table 5 shows comparative data between $PaCO_2$ and $TcPCO_2$ for the entire population (Figure 2B) and for patients grouped according to the severity of respiratory dysfunction.

TABLE 3
Description of the Study Population (n=130)*

Variable	Mean (SD)
Age, years	64.2 (13.4)
Height, cm	163.3 (9.3)
Weight, kg	79.2 (16.6)
FEV_1, L	1.8 (1.0)
FEV_1, % theoretical	61.9 (27.4)
FVC, L	2.9 (1.1)
FVC, % theoretical	72.9 (19.8)
FEV_1/FVC, %	60.8 (17.7)
Mean $PaCO_2$, mm Hg	42.2 (7.2)
Mean SaO_2, %	93.5 (4.4)

*FEV_1 indicates forced expiratory volume in 1 second; FVC, forced vital capacity; SaO_2, oxygen saturation

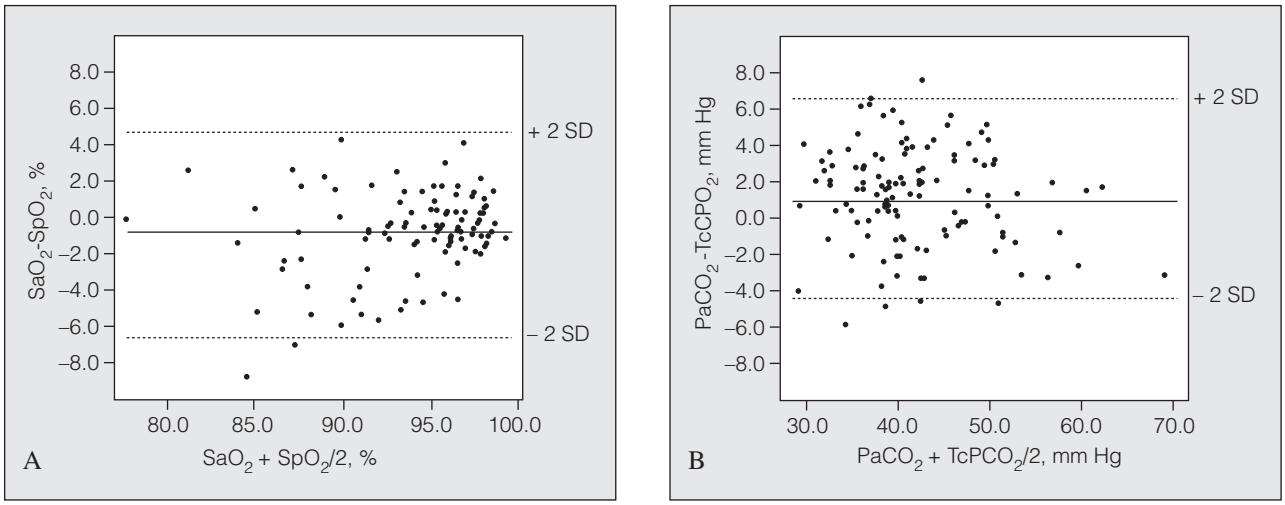

Figure 3. ***A:*** **Bland-Altman plot of values of oxygen saturation obtained by arterial blood gas analysis (SaO_2) and with the V-Sign™ monitor (SenTec Inc, Therwil, Switzerland) (SpO_2).** ***B:*** **Bland-Altman plot of values of $PaCO_2$ obtained by arterial blood gas analysis and the transcutaneous measure obtained with the V-Sign™ monitor ($TcPCO_2$).**

The extent of dispersion was analyzed by means of a Bland-Altman plot for the SaO_2 and SpO_2 values (Figure 3A) and for the $PaCO_2$ and $TcPCO_2$ values (Figure 3B).

Discussion

Towards the end of the 1990s and at the beginning of this decade, Rohling and Biro[6] and Tschupp and Fanconi[8] published the first articles on a monitor that incorporated the elements of an optical pulse oximetry sensor with a Severinghaus-type $PaCO_2$ sensor.[14] The monitor worked by heating the skin in contact with the measuring electrode to increase the local blood flow. The monitor minimized the drawbacks of the traditional devices described in Table 1 in that the stabilization time was shorter (15-20 min), response was quicker ($TcPCO_2$ values lagged behind changes in $PaCO_2$ by 1-2 min), and electrodes with lower working temperatures (between 39ºC and 42ºC) were used.[15] Monitors that measure PaO_2 and $PaCO_2$ work at higher temperatures (≥45ºC) and so may burn the patient's skin if the application site of the sensor is not changed. Given that the type of monitor that we evaluated works at lower temperatures, burns should not, in principle, be a problem.

TABLE 4
Comparison of Oxygen Saturation Levels Obtained in the Arterial Blood Gas Analysis (SaO_2, Mean of 2 Measurements) and With the V-Sign™ Monitor (SpO_2)*

	No. Patients	SaO_2, %	SpO_2, %	ICC†	MD (CI)
Overall population	130	93.5 (4.4)	94.3 (4.5)	0.73	–0.89 (from –1.43 to –0.33)
FEV_1 ≥80%	40	96.6 (1.9)	96.7 (1.9)	0.52	–0.09 (from –0.68 to 0.49)
FEV_1 60%-79%	23	95.2 (2.6)	95.2 (4.3)	0.39	0.04 (from –1.65 to 1.70)
FEV_1 40%-59%	30	92.6 (3.9)	94.4 (4.1)	0.69	–1.82 (from –2.87 to –0.78)
FEV_1 <40%	37	89.7 (4.6)	91.2 (5.1)	0.67	–1.50 (from –2.80 to –0.30)

*SenTec Inc, Therwil, Switzerland.
FEV_1 indicates forced expiratory volume in 1 second; N, number of patients; ICC, intraclass correlation coefficient; MD, mean difference SaO_2-SpO_2; CI, confidence interval.
†P<.03 in all cases.

TABLE 5
Comparison of Readings of Partial Pressure of Carbon Dioxide Obtained in the Arterial Blood Gas Analysis ($PaCO_2$, Mean of 2 Measurements) and With the V-Sign™ Monitor ($TcPCO_2$)*

	No. Patients	$PaCO_2$, mm Hg	$TcPCO_2$, mm Hg	ICC†	MD (95% CI)
Overall population	130	42.16 (7.2)	41.2 (7.6)	0.92	0.99 (0.5-1.47)
FEV_1 ≥80%	40	38.48 (3.5)	37.2 (3.9)	0.68	1.22 (0.33-2.1)
FEV_1 60-79%	23	38.11 (4.1)	37.4 (3.7)	0.77	0.64 (from –0.47 to 1.7)
FEV_1 40-59%	30	43.14 (7.2)	42.2 (7.9)	0.90	0.89 (from –0.3 to 2.1)
FEV_1 <40%	37	47.86 (7.8)	46.8 (8.3)	0.94	1.02 (0.15-1.9)

*SenTec Inc, Therwil, Switzerland.
FEV_1 indicates forced expiratory volume in 1 second; ICC, intraclass correlation coefficient; MD, mean difference $PaCO_2$-$TcPCO_2$; CI, confidence interval.
†P<.00001 in all cases.

The stabilization time established empirically according to the judgment of the nurse who took the readings was 14 (3) minutes. A reasonable recommendation for use of the SenTec monitor would therefore be to take readings 20 minutes after attaching the sensor, and certainly never before 15 minutes have elapsed. None of the patients in our population were smokers and all were white and free of jaundice; thus factors that have been shown to affect the results of pulse oximetry were eliminated.[2]

Arterial blood gas analysis was done in accordance with SEPAR guidelines.[12] To avoid systematic calibration errors of the analyzers, we processed our samples in 2 different analyzers and took the mean of the values obtained as the reference arterial blood gas value. As reflected by the results of comparison of the 2 blood gas analyses (in the pulmonology clinic and the ICU), the reference value (that is, the mean arterial blood gas value) was completely reliable (the mean differences between the values obtained with the 2 analyzers were minimal).

Measurements are a fundamental part of both clinical practice and investigation. Repeated measurements of the same variable in the same subject do not usually yield the same value. This can be due to natural variations in the subject, variations in the measurement process, or both.[16] Therefore, statistical methods to calculate the error are important. As a first approximation, the Pearson correlation coefficient was calculated to compare the results of the reference technique (arterial blood gas analysis) with the new method (SenTec monitor). The results were also represented graphically with a scatter plot (Figures 2A and 2B).[17] The Pearson correlation coefficient measures the strength of linear association of 2 variables and indicates how the values of one of these vary as a function of the other. With this test we can discard the negative hypothesis, that is, that there is no linear association between the 2 measurements (the reference measurement and the measurement for validation). A strong correlation, however, does not necessarily mean that the 2 measurements agree.[17,18] To validate a technique, we must not only show that the 2 variables vary in the same direction but that they do so in the same way.

The reliability of a device or method of analysis should be evaluated with tests of agreement. A number of authors have suggested that the ICC can provide a measure of agreement for continuous variables. This coefficient is not subject to the problems inherent in the linear correlation coefficient (it does not depend on the range of values of the sample and the result is unaffected by the order in which the readings are presented or variability among subjects, although changes in measurement scales do have an effect).[19,20] It is also an excellent indicator of reliability of the measurement.[18,19] Currently, most authors recommend using the ICC to quantify the reliability of clinical measurements.[21] We also used this coefficient, and the results were as satisfactory as could be hoped. We took an agreement to be good when ICC was between 0.71 and 0.9,[20] as was the case for SaO_2, and very good when it exceeded 0.9,[20] as was the case for $PaCO_2$.

Bland and Altman[17] proposed a simple though subjective[21] graphical method to assess the agreement between 2 measurement systems. The method consists of plotting the differences between 2 measures against their mean value. The confidence interval of the mean difference indicates whether or not the values are systematically over- or underestimated. Should a systematic error be detected, it is up to the clinician to decide whether this error is relevant. In our case, we observed that the SenTec monitor systematically underestimated the values for SaO_2 by about 1% and overestimated those of $PaCO_2$ by about 1 mm Hg—differences which are not clinically relevant. The subgroup analysis did not provide any relevant additional information. Another concept is that of the limits of agreement, which are the confidence intervals for the mean differences. According to statistical theory, the interval comprising 2 SD either side of the mean (in this case, the mean difference) includes 95% of the differences observed. Figures 3A and 3B show that almost all the values obtained were within 2 SD, and so, from a statistical point of view, we can conclude that monitor is reliable. Finally, the Bland-Altman plot[19] shows that the dispersion remained constant over the range of $PaCO_2$ and SaO_2 values.

A correct interpretation of the Bland-Altman[19] analysis, however, requires us to establish whether the differences observed are clinically relevant or not.[20] For SaO_2, almost all variations were less than 5%, as is the case for most pulse oximeters.[2,8,22] For $PaCO_2$, the mean difference was approximately 1 mm Hg, which is not particularly important for the management of most patients with respiratory disorders, particularly if they are stable. Given that the study population comprised stable patients at rest, we cannot extrapolate our results to patients on oxygen therapy or mechanical ventilation.

The most important limitation of the SenTec monitor is its lack of memory, which means it cannot be used to record nighttime values. The monitor is therefore limited to measurements in real time. Versions of the monitor that overcome this drawback are expected to be available shortly. It should also be remembered that this monitor is more complicated to use than a traditional pulse oximeter and there is therefore a learning curve. The sensor membrane should be changed every 15 days, the level of the calibration gas checked regularly, the stabilization time (of around 20 minutes, as we indicated earlier) respected, and care taken to avoid measurement errors arising from electrolyte depletion or poor contact between the clip and the skin. The weight, size, and stabilization time of the monitor are such that it can be used in stable outpatients as well as hospital patients. For patients with severe decompensation, particularly in an outpatient setting, the stabilization time is a limitation to be remembered.

Our results are similar to those of Kocher et al,[23] although the confidence interval for $PaCO_2$ in our study

was slightly greater. In Spain, findings similar to our own have been reported recently,[24] but in a small population. We believe that the current model of the SenTec monitor is useful as a noninvasive monitoring tool that provides an alternative to arterial blood gas analysis for measuring $PaCO_2$ at discrete times. The monitor should help improve diagnosis and therapy in many patients in the coming years.[25]

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