

Multicenter Study Validating Accuracy of a Continuous Respiratory Rate Measurement Derived From Pulse Oximetry: A Comparison With Capnography

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BACKGROUND: Intermittent measurement of respiratory rate via observation is routine in many patient care settings. This approach has several inherent limitations that diminish the clinical utility of these measurements because it is intermittent, susceptible to human error, and requires clinical resources. As an alternative, a software application that derives continuous respiratory rate measurement from a standard pulse oximeter has been developed. We sought to determine the performance characteristics of this new technology by comparison with clinician-reviewed capnography waveforms in both healthy subjects and hospitalized patients in a low-acuity care setting.

METHODS: Two independent observational studies were conducted to validate the performance of the Medtronic Nellcor™ Respiration Rate Software application. One study enrolled 26 healthy volunteer subjects in a clinical laboratory, and a second multicenter study enrolled 53 hospitalized patients. During a 30-minute study period taking place while participants were breathing spontaneously, pulse oximeter and nasal/oral capnography waveforms were collected. Pulse oximeter waveforms were processed to determine respiratory rate via the Medtronic Nellcor Respiration Rate Software. Capnography waveforms reviewed by a clinician were used to determine the reference respiratory rate.

RESULTS: A total of 23,243 paired observations between the pulse oximeter-derived respiratory rate and the capnography reference method were collected and examined. The mean reference-based respiratory rate was 15.3 ± 4.3 breaths per minute with a range of 4 to 34 breaths per minute. The Pearson correlation coefficient between the Medtronic Nellcor Respiration Rate Software values and the capnography reference respiratory rate is reported as a linear correlation, R , as 0.92 ± 0.02 ($P < .001$), whereas Lin's concordance correlation coefficient indicates an overall agreement of 0.85 ± 0.04 (95% confidence interval [CI] +0.76; +0.93) (healthy volunteers: 0.94 ± 0.02 [95% CI +0.91; +0.97]; hospitalized patients: 0.80 ± 0.06 [95% CI +0.68; +0.92]). The mean bias of the Medtronic Nellcor Respiration Rate Software was 0.18 breaths per minute with a precision (SD) of 1.65 breaths per minute (healthy volunteers: 0.37 ± 0.78 [95% limits of agreement: -1.16; +1.90] breaths per minute; hospitalized patients: 0.07 ± 1.99 [95% limits of agreement: -3.84; +3.97] breaths per minute). The root mean square deviation was 1.35 breaths per minute (healthy volunteers: 0.81; hospitalized patients: 1.60).

CONCLUSIONS: These data demonstrate the performance of the Medtronic Nellcor Respiration Rate Software in healthy subjects and patients hospitalized in a low-acuity care setting when compared with clinician-reviewed capnography. The observed performance of this technology suggests that it may be a useful adjunct to continuous pulse oximetry monitoring by providing continuous respiratory rate measurements. The potential patient safety benefit of using combined continuous pulse oximetry and respiratory rate monitoring warrants assessment. (Anesth Analg 2017;124:1153-9)

Abnormalities in respiratory rate are often an indicator of acute respiratory compromise and/or ensuing deterioration in a patient's condition. Respiratory

rates less than 6 or greater than 30 breaths per minute are associated with increased mortality in patients on the general care floor.¹ Changes in respiratory rate may precede changes in other respiratory parameters such as arterial oxygen saturation,² suggesting that monitoring respiratory rate may provide more expedient alerts to changes in clinical condition.

Current approaches to measuring and monitoring respiratory rate, however, limit the ability of respiratory rate changes to prompt additional clinical assessment. Technologies broadly used to measure respiratory parameters in hospital and clinical settings typically rely on pulse oximetry, capnography (end-tidal CO₂), and transthoracic impedance (TTI) through echocardiogram electrodes.^{3,4} Pulse oximetry, however, is a lagging indicator of hypoventilation in patients with decreased oxygen saturation, usually after a few minutes of the respiratory depression episode starting.⁵ In contrast, capnography has a few well-documented technical and physiological limitations for nonintubated

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patients; the measurement of parameters of ventilation could be altered with the placement of the cannula sensor, fresh gas flow rate, and tidal volume.^{5,6} TTI is another reference method used to detect breaths, but it is very sensitive to movements and could generate disturbances of the TTI reference signal. In addition this technique often is used only in patients who require cardiac monitoring.⁷

Although continuous noninvasive monitoring is available for other physiologic parameters such as heart rate and arterial oxygen saturation, intermittent manual assessment of respiratory rate remains common in clinical practice.^{8,9} This method, however, frequently is inaccurate, even when implemented by trained clinicians, and leaves respiratory rate unmonitored for long periods of time.¹⁰ Consequently, the likelihood that abnormalities in respiratory rate will be detected and promptly responded to is low. Thus, a monitoring method that continuously and accurately measures respiratory rate may have substantial clinical utility and patient benefit.

Deriving a measurement of respiratory rate from a pulse oximeter is a technological approach that may overcome these limitations. The photoplethysmogram waveform obtained by pulse oximeters varies during spontaneous breathing.^{11,12} Changes in venous return, stroke volume, and respiratory sinus arrhythmia that result from respiratory-induced hemodynamic and autonomic neural modulations produce subtle changes in the photoplethysmogram waveform.¹³ Other groups previously have demonstrated that evaluating these respiratory-related fluctuations from the photoplethysmogram signal is both a biologically plausible and technically attainable approach to measuring respiration rate.¹⁴⁻²¹ Because pulse oximetry is used broadly in the hospital setting and continuous pulse oximetry monitoring is beneficial in some general care settings, the addition of continuous respiratory rate monitoring may augment the clinical benefits without adding substantial burden of work or cost to health care professionals and their institutions.

Recently, an algorithm to derive respiratory rate measurements from the photoplethysmogram was described.^{22,23} The algorithm has been incorporated into a commercially available software application that reports respiratory rate continuously from a standard pulse oximeter. We characterized the performance of this software application in healthy subjects and patients hospitalized in a low-acuity care setting to obtain regulatory clearance. We hypothesized that the Nellcor™ Respiration Rate Software (Medtronic, Boulder, CO) would report respiratory rate within 3 breaths per minute of the capnography reference.

METHODS

Study Details

With institutional review board approval and written informed consent from all subjects, 2 independent observational studies were conducted. The studies sought to determine the performance characteristics of the Medtronic Nellcor Respiration Rate Software application in healthy volunteers and patients hospitalized in a low-acuity care setting. The first study enrolled healthy volunteer subjects at the Medtronic Respiratory & Monitoring Solutions clinical laboratory (ClinicalTrials.gov identifier: NCT01294514; PI: Dr

Scott Kelley, Registration Date: February 10, 2011). Subjects were free of overt cardiovascular, pulmonary, and metabolic diseases, and they were not taking any prescription medications. The second multicenter study enrolled a convenience sample of adult patients hospitalized at the Ohio State University Medical Center and the University of Colorado Hospital (ClinicalTrials.gov identifier: NCT0130620; PIs: Dr Sergio Bergese and Dr Robert McIntyre, Registration Date: February 10, 2011). Patients were ≥ 18 years old and had been admitted to the general or ward care areas of the hospital. No specific disease states or pathophysiologic conditions were targeted during enrollment. Exclusion criteria were (1) known severe contact allergies, (2) skin or digit abnormalities preventing proper application of a pulse oximeter sensor, (3) pregnant or lactating women, and (4) cardiac arrhythmias, including atrial fibrillation, defined as ≥ 3 irregularities within 30 seconds documented by palpation of peripheral pulse or observation on electrocardiographic monitoring.

Protocol

Study data were collected during a 30-minute observation period. All subjects and patients were spontaneously breathing and unaware that respiratory rate was being measured. Research personnel observed subjects during the study period and recorded any subject movement or other events during data collection to ensure data quality.

Photoplethysmography data were acquired with a Nellcor™ OxiMax N-600x Pulse Oximeter (Medtronic) monitor via an adult Nellcor™ Adult Respiratory Rate Sensor (Medtronic) affixed to an index finger. These data were analyzed by the software application (Medtronic Nellcor Respiration Rate Software; Medtronic, Dublin, Ireland) running on a tablet device connected to the oximeter by serial cable. The analysis was done automatically by the respiration rate software, free from user intervention, system configuration (which remained identical for all subjects), or any manipulation of the device operation. The device computed and reported a respiratory rate from the incoming pulse oximeter data, in real time, from a 45-second window of data once every 5 seconds.²²

Capnography waveform data were collected simultaneously via a nasal/oral sampling catheter (Smart CapnoLine Plus; Oridion, Needham, MA) connected to a multiparameter monitor equipped with Microstream capnography (CAS Medical 750E; CAS Medical, Branford, CT). Photoplethysmography and capnography data were collected from device serial ports using Acumen Data Loggers (Acumen Instruments, Ames, IA) and stored on compact flash cards for analysis. A digital timer recorded time of events during data collection and ensured synchronization between the monitoring devices.

Reference Respiratory Rate Determination

Capnography waveforms were reviewed by a single anesthesiologist to determine true breaths. The anesthesiologist was blinded to all other study data. The respiratory rate was calculated by determining the number of breaths on a capnography trace during a given epoch of time (eg, 1 minute). The reference respiratory rate was recalculated every 5 seconds.

Statistical Analyses

Consistent with existing literature, we describe the mean bias of the software application with respect to the capnography reference as accuracy, whereas precision refers to the standard deviation of the errors of the measurements. We also report root mean square deviation (RMSD), a measure used for pulse oximetry-based parameters such as SpO₂ and pulse rate that combines both mean bias (mean error) and precision (SD error) to give a total error measure consistent with the ISO80601-2-61 standard.²⁴ RMSD was computed as follows: $([\sum \{RR_{\text{Respiration Rate Software}} - RR_{\text{Capnography}}\}^2 / n])^{1/2}$, where $RR_{\text{Respiration Rate Software}}$ is the device under test, $RR_{\text{Capnography}}$ is the reference device, and n is the number of data points. We have adopted this in lieu of a standard for pulse oximetry-derived respiratory rate measurements.

Recognizing the risk of longitudinal correlation, an analysis by components of variance technique was followed, as described by Bland and Altman.²⁵ This method compensates for multiple measurements being taken from the same subject when the true reference value is changing. A modified Bland–Altman diagram was used to graphically represent the data, displaying mean bias and limits of agreement. Here, the usual abscissa of the Bland–Altman diagram (the mean of the 2 independent observations) is replaced by one of the reference measurements. That is, the reference is assumed to have negligible error and so forms the x -axis of the plot.

Lin's concordance correlation coefficient is presented as a single-number summary of agreement, whereas the Pearson-product moment correlation coefficient is presented as an indication of linear correlation between the observations and reference. We have used a sampling with substitution bootstrap methodology to minimize the effects of longitudinal correlation and present these data as the expected value \pm the SE. We assumed a normal approximation interval ($\alpha = .05$) to compute the 95% confidence interval (95% CI) for these coefficients.

Statistical significance was set a priori at $P < .05$ for all relevant analyses. Analyses were performed using MatLab Version R2011a (MathWorks, Natick, MA).

The required sample size was powered to test the primary hypothesis that the Medtronic Nellcor Respiration Rate Software reported respiration rate with a mean RMSD of less than 3 breath rate per minute across subjects. To determine sample size, a 1 sample, 2-sided Student t test analysis was performed using data from a controlled laboratory environment, where 194 healthy volunteer subjects showed a mean \pm SD of 1.40 ± 1.44 . In the less-controlled hospital environment, the mean and SD used to determine the sample size was 2.27 ± 1.82 , respectively, based on 51 previously collected general care floor patients. Analysis based on these studies resulted in a requirement of 22 healthy volunteers and 51 general care floor patients for 80% power at the .05 significance level.

RESULTS

A total of 90 subjects and patients were enrolled in the studies. Five were excluded due to the presence of arrhythmias, and 6 were excluded due to corrupted files during acquisition of data. Data from the remaining 79 volunteer subjects

and hospital patients were analyzed. Selected demographic characteristics for the volunteer and hospital studies are presented in Table 1. Body mass indices of the hospitalized cohort ranged from 15.2 to 47.9 kg/m² with 36% and 11.3% of these patients being classified as obese and morbidly obese, respectively. Medical conditions of the hospitalized patients are listed in Table 2. The most common medical conditions of hospital patients were hypertension and obesity, occurring in 45% and 36% of patients, respectively.

Data were collected from 26 volunteer subjects and 53 hospital patients for 29.6 ± 0.8 minutes. A respiratory rate was determined from both the reference and the Medtronic Nellcor Respiration Rate Software every 5 seconds for each subject to produce a paired respiratory rate measurement. A total of 12.3% of data were excluded per protocol due to documented motion interference noted on the case report form. An additional 2.6% of data were excluded because the capnography waveform data were determined to be unreadable. Half a percent of the monitored data were excluded because of the software application not producing a respiratory rate value. In total, 23,243 paired respiratory rate measurements (Medtronic Nellcor Respiration Rate Software versus capnography reference) were used for the analysis.

Reference and Medtronic Nellcor Respiration Rate Software data are presented in Table 3. Reference respiratory rate was 15.3 ± 4.3 breaths per minute with a range of 4 to 34 breaths per minute. Relative to baseline, the respiratory rate varied during the data collection period by 6.2 ± 2.8 breaths per minute, representing a variation of 62.7% (Table 4). The Pearson-product moment coefficient shows the linear correlation between the Medtronic Nellcor Respiration Rate Software and the reference respiratory rate as $R = 0.92 \pm 0.02$ ($P < .001$; Figure 1). The Lin's concordance correlation coefficient indicates an overall agreement of 0.85 ± 0.04 (95% CI +0.76; +0.93) (healthy volunteers: 0.94 ± 0.02 [95% CI +0.91; +0.97]; hospitalized patients: 0.80 ± 0.06 [95% CI +0.68; +0.92]).

The mean bias accuracy of the Medtronic Nellcor Respiration Rate Software was 0.18 breath per minute and SD was ± 1.65 breaths per minute. The RMSD was 1.35 breaths per minute. The 95% limits of agreement (mean bias $\pm 1.96 \times$ SD) were -3.06 and 3.42 breaths per minute as shown in Figure 2 (healthy volunteers: 0.37 ± 0.78 breaths per minute [limits of agreement: -1.16 ; $+1.90$]; hospitalized patients: 0.07 ± 1.99 breaths per minute [limits of agreement: -3.84 ; $+3.97$] breaths per minute). See Table 3. With respect to the study's original accuracy hypothesis, in controlled laboratory conditions, 99% of measurements from healthy volunteers reported within 3 breaths per minute of the respiration rate reference. In the less-controlled hospital environment, 91% of measurements reported within 3 breaths per minute of the respiration

Table 1. Selected Volunteer Subject and Hospital Patient Characteristics

Variable	Volunteer Subjects (N = 26)	Hospital Patients (N = 53)
Age (y)	36.0 \pm 9.7	47.2 \pm 15.4
Gender (M/F)	11/15	20/33
Weight (kg)	71.4 \pm 11.8	85.5 \pm 30.2
Height (m)	1.7 \pm 0.1	1.7 \pm 0.1
Body mass index (kg/m ²)	24.2 \pm 2.7	30.2 \pm 11.9

Values are presented as mean \pm SD.

Table 2. Medical Conditions in Hospitalized Patients	
	n
Cardiovascular	
Hypertension	24
Deep venous thrombosis (DVT)	4
Coronary artery disease	3
Congestive heart failure	2
Previous myocardial infarction	2
Fluid overload and /or venous insufficiency	2
Asymptomatic bradycardia	1
Diastolic dysfunction	1
Mitral valve endocarditis	1
Orthostatic hypotension	1
Superior vena cava stenosis	1
Respiratory	
Asthma	7
Chronic obstructive pulmonary disease	3
Obstructive sleep apnea	2
Previous pulmonary embolism	2
Cystic fibrosis	1
Reactive airway disease	1
Endocrine/metabolic	
Obesity	19
Morbid obesity	6
Hyperlipidemia	9
Hypothyroidism	9
Diabetes mellitus (type I or type II)	7
Thyroid cancer	3
Growth hormone deficiency	1
Multiple endocrine neoplasm-1 syndrome	1
Previous pancreatic transplant	1
Gastrointestinal	
Gastroesophageal reflux disease	9
Diverticulitis	5
Bowel obstruction	3
Crohn disease	3
Gastroparesis	2
Intra-abdominal abscess/anal fistula	2
Rectal cancer	2
Appendicitis	1
Barrett's esophagus/carcinoma in situ	1
Ulcerative colitis	1
Renal	
Previous renal transplant	5
End-stage renal disease	4
Uremia/renal insufficiency	4
Chronic kidney disease	2
Renal mass	2
Amyloidosis	1
Hyperphosphatemia	1
Metabolic acidosis	1
Adrenal neoplasm	1
Genitourinary	
Urinary tract infection	6
Breast cancer	3
Ovarian cancer	3
Bladder cancer	1
Flank pain/hematuria	1
Epididymo-orchitis	1
Testicular cancer	1
Pelvic hematoma	1
Lymphocele	1
Hematology	
Anemia	6
Avascular necrosis	1
Idiopathic thrombocytopenic purpura	1
Sickle cell pain crisis	1

(Continued)

Table 2. (Continued)	
	n
Infections	
Cellulitis	2
Chronic bulbar poliomyelitis	1
HIV	1
Hepatitis C	1
Hepatobiliary	
Liver/gallbladder mass	3
Cholecystitis/choledocholithiasis	2
Cirrhosis	2
Musculoskeletal and connective tissue	
Chronic lower extremity ulcer	1
Degenerative joint disease	1
Neurologic	
Migraine headache	3
Hepatic encephalopathy	1
Peripheral Neuropathy	1
Multiple sclerosis	1
Seizure disorder	1
Peritoneal/Retroperitoneal	
Primary peritoneal adenocarcinoma	1
Retroperitoneal liposarcoma	1
Psychiatric	
Anxiety/depression	6
Bipolar disorder	3

Table 3. Medtronic Nellcor Respiration Rate Software Performance Characterization Data			
Variable	Volunteers (n = 26)	Patients (n = 53)	Combined (N = 79)
RR Reference (BrPM)	13.8 ± 3.2	16.0 ± 4.6	15.3 ± 4.3
RR Software (BrPM)	13.2 ± 3.0	15.4 ± 4.0	14.7 ± 3.8
Bias (BrPM)	0.37	0.07	0.18
SD (BrPM)	± 0.78	± 1.99	± 1.65
Root mean square deviation (BrPM)	0.84	1.60	1.35
95% limits of agreement	(-1.16; +1.90)	(-3.84; +3.97)	(-3.06; +3.42)

Abbreviations: BrPM, breaths per minute; RR, respiratory rate.

Table 4. Respiratory Rate Variability From Baseline			
Correlation Coefficient	Volunteers (n = 26)	Patients (n = 53)	Combined (N = 79)
Pearson linear	0.97 ± 0.01 (+0.96, +0.99)	0.90 ± 0.03 (+0.83, +0.96)	0.92 ± 0.02 (+0.87, +0.97)
Lin's concordance	0.94 ± 0.02 (+0.91, +0.97)	0.80 ± 0.06 (+0.68, +0.92)	0.85 ± 0.04 (+0.76, +0.93)
Variable	Mean ± SD	Minimum	Maximum
Relative change in respiratory rate (BrPM)	6.2 ± 2.8	2.0	13.7
Relative change in respiratory rate (%)	62.8 ± 47.8	14.3	271.4

Abbreviation: BrPM, breaths per minute.

rate reference. Overall, 94% of measurements reported within 3 breaths per minute of the respiration rate reference.

DISCUSSION

These results demonstrate that the Medtronic Nellcor Respiration Rate Software application reports respiratory

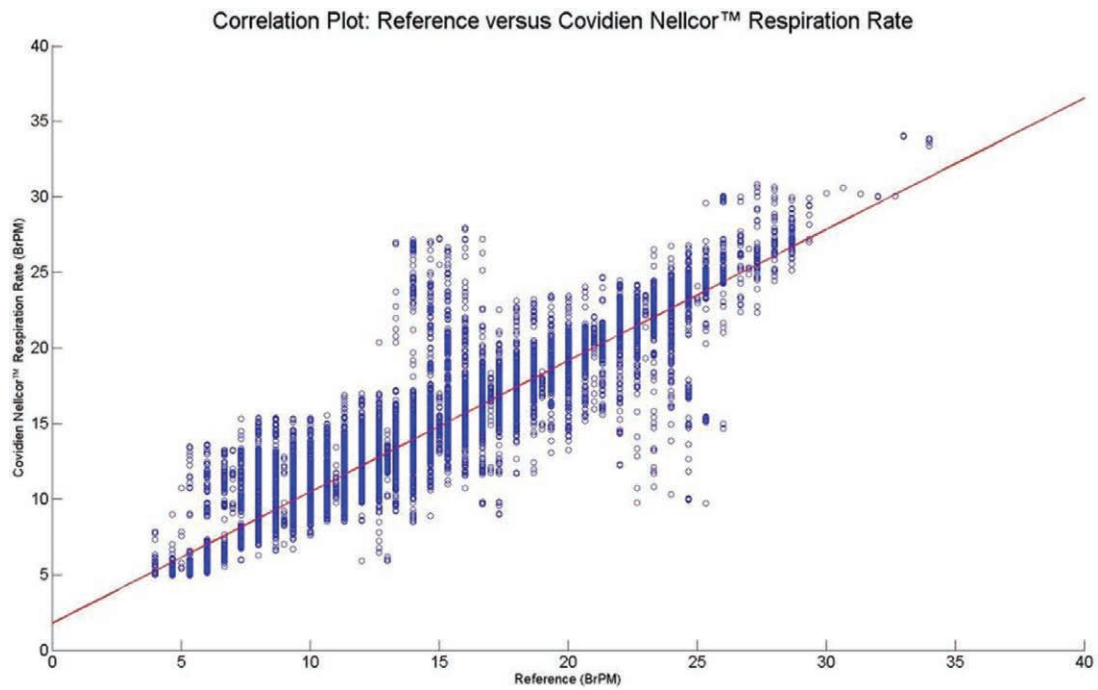


Figure 1. Relation between Nellcor Respiration Rate Software and the capnography reference ($R = 0.92$; $P < .001$).

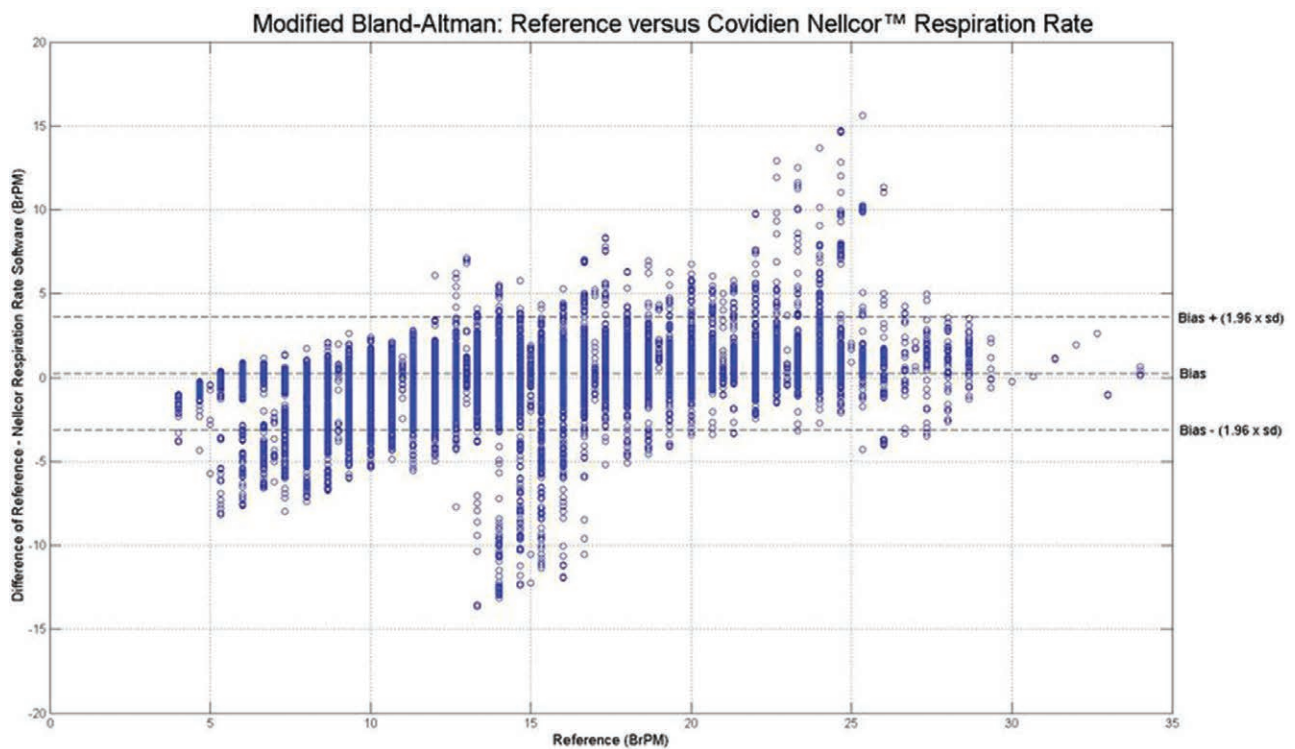


Figure 2. Modified Bland–Altman of Nellcor Respiration Rate Software versus capnography reference ($N = 23,243$ paired observations).

rate measurements within 3 breaths per minute, as measured by RMSD, to reference measurements from capnography waveform analysis under controlled conditions. Based on our study hypothesis, the Medtronic Nellcor Respiration Rate Software application provides a substantially equivalent means of continuously measuring respiratory rate in healthy subjects and patients hospitalized in a low-acuity setting from

a pulse oximeter waveform. This application warrants further investigation to assess how it may enhance current monitoring capabilities by providing continuous respiratory rate information in combination with arterial oxygen saturation.

Respiratory rate is monitored routinely through observational assessment. The accuracy of this technique, however, often is poor, even when performed by trained clinicians.¹⁰

The development of automated respiratory rate monitoring modalities may alleviate this problem by providing more accurate and objective measurements.²⁶ In comparison with a clinician-reviewed capnography waveform-based reference respiratory rate, the Medtronic Nellcor Respiration Rate Software has a mean bias and limits of agreement of 0.18 ± -3.06 and 3.42 breaths per minute. Our hypothesis that performance within ± 3 breaths per minute of the reference device reflects substantial equivalence is based on the assumption that normative clinical values for respiratory rate are given in ranges, as opposed to exact values.⁸ The reporting accuracy thus needs to be within a clinically reasonable range and not exact. The results of the present study are comparable with the reported performance of other noninvasive continuous respiratory rate technologies. For example, Mimoz et al²⁷ reported that the mean bias and limits of agreement for an acoustic-based measurement technique were 0 and ± 1.4 breaths per minute, respectively, when compared with a capnography reference measurement in patients in the postanesthesia care unit. The difference in limits of agreement in the studies may result from our use of a modified Bland–Altman analysis, wherein the capnography reference was not averaged with the experimental (Medtronic Nellcor Respiration Rate Software) respiratory rate value to determine the limits of agreement.

Most assessments of patient respiratory rate are performed on an intermittent basis (eg, every 2–4 hours) and current guidelines recommend measuring respiratory rate for a 1-minute period by visual observation or auscultation.⁸ Thus, routine respiratory rate assessments leave this parameter unmonitored for the majority of the time in most clinical care settings. Abnormalities in respiratory rate preceding clinically untoward events, therefore, may go undetected, underscoring the need for continuous respiratory rate monitoring capabilities.²⁸ Novel technologies capable of producing respiratory rate measurements have the potential to provide further information to clinicians if they are continuous in nature and well-tolerated by patients. In this study, we demonstrated that the technology tested reported a respiratory rate value for more than 99% of the study data not excluded by interference per protocol. With respect to interference, 12.3% of data were excluded, per study protocol, due to expected motion interference recorded by research staff in the clinical settings. In addition, no subject or patient removed the sensor due to physical discomfort or annoyance.

The clinical applications of continuous respiratory rate monitoring are, currently, not completely understood. McGrath et al²⁹ recently reported that respiratory rates lower than 6 breaths per minute occurred in <1% of a sample that included data from a low-acuity hospital setting. In contrast, respiratory rates over 20 breaths per minute were observed in more than 20% of data, but they did not report that high respiratory rates were associated with adverse events. Churpek et al³⁰ studied Modified Early Warning Score and individual vital sign prediction of cardiac arrest on the general care floor and reported that of all vital signs considered individually, maximum respiratory rate was the best predictor in this setting. Together, these studies suggest that elevations in respiratory rate may be more common than previously thought and could be predictive of respiratory compromise and other forms of clinical deterioration.

Study Limitations

There are several important limitations in this study. First, the hospitalized cohort enrolled in this study was a convenience sample. Although this sample resulted in wide array of cardiovascular, respiratory, and metabolic/endocrine disorders, other medical conditions or pathophysiologic states that may influence the performance of this technology may not have been included in the study cohort. In addition, our study was conducted with the use of carefully controlled conditions to assess accuracy and did not include conditions such as patient motion or low perfusion states. Finally, subjects and patients in the present study were breathing spontaneously and were not instructed to alter their respiratory rates. Thus, the observed results may not be generalizable to all patient populations. Additional studies are required to determine the accuracy of the application in specific medical conditions, at extremes of respiratory rate and response times during rapid changes in respiratory rate.

In aggregate, these data demonstrate that the Medtronic Nellcor Respiration Rate Software application linked to a standard pulse oximeter is able to measure respiratory rate within 3 breaths per minute of the capnography-based reference in healthy subjects and low-acuity hospitalized patients. The use of this application for continuously monitoring respiratory rate concomitant with oxygen saturation warrants future studies to determine the clinical utility of this combined platform of respiratory monitoring. ■

DISCLOSURES

Name: Sergio D. Bergese, MD.

Contribution: This author helped design the study, collect data, and prepare the manuscript.

Conflicts of Interest: Sergio D. Bergese reports receiving research support from Medtronic.

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Contribution: This author helped analyze and interpret the data and prepare the manuscript.

Conflicts of Interest: Michael L. Mestek reports employment with Medtronic.

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Contribution: This author helped design the study, collect and analyze the data, and prepare the manuscript.

Conflicts of Interest: Scott D. Kelley reports previous employment with Medtronic.

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