ORIGINAL ARTICLE

Accuracy of acoustic respiration rate monitoring in pediatric patients

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Summary

Background: Rainbow acoustic monitoring (RRa) utilizes acoustic technology to continuously and noninvasively determine respiratory rate from an adhesive sensor located on the neck.

Objective: We sought to validate the accuracy of RRa, by comparing it to capnography, impedance pneumography, and to a reference method of counting breaths in postsurgical children.

Methods: Continuous respiration rate data were recorded from RRa and capnography. In a subset of patients, intermittent respiration rate from thoracic impedance pneumography was also recorded. The reference method, counted respiratory rate by the retrospective analysis of the RRa, and capnographic waveforms while listening to recorded breath sounds were used to compare respiration rate of both capnography and RRa. Bias, precision, and limits of agreement of RRa compared with capnography and RRa and capnography compared with the reference method were calculated. Tolerance and reliability to the acoustic sensor and nasal cannula were also assessed.

Results: Thirty-nine of 40 patients (97.5%) demonstrated good tolerance of the acoustic sensor, whereas 25 of 40 patients (62.5%) demonstrated good tolerance of the nasal cannula. Intermittent thoracic impedance produced erroneous respiratory rates (>50 b·min^{-1} from the other methods) on 47% of occasions. The bias $\pm$ SD and limits of agreement were -0.30 ± 3.5 b·min^{-1} and -7.3 to 6.6 b·min^{-1} for RRa compared with capnography; -0.1 ± 2.5 b·min^{-1} and -5.0 to 5.0 b·min^{-1} for RRa compared with the reference method; and 0.2 ± 3.4 b·min^{-1} and -6.8 to 6.7 b·min^{-1} for capnography compared with the reference method.

Conclusions: When compared to nasal capnography, RRa showed good agreement and similar accuracy and precision but was better tolerated in postsurgical pediatric patients.

Introduction

Respiratory complications after anesthesia and during opioid analgesic therapy occur commonly in children. Ideally, monitoring respirations during the perioperative period would be able to detect respiratory abnormalities to allow interventions before frank complications occur. Currently, respiration monitoring possesses limitations.

Continuous monitoring of ventilation and oxygenation can detect respiratory complications before they result in cardiopulmonary arrest, but monitoring of oxygen saturation alone does not provide an indication of the patient's ventilation, and hypoxia is a late indicator of hypoventilation especially when supplemental oxygen is administered (1). Respiratory rate monitoring detects early respiratory distress (2), and several methods of

respiratory rate measurement are currently used (transthoracic impedance, sidestream capnography, and manual counting of breaths). Transthoracic impedance analyzes chest movement to measure respiratory rate. Although this is the standard of care in many institutions for monitoring respiration in pediatric patients, common problems include inaccuracy and high incidence of false alarms (3). Sidestream capnography was found to be more accurate than thoracic impedance monitoring in adults (4), but the acceptance of nasal cannula by young children is a concern. Manual counting of the respiratory rate is noncontinuous and often misses the detection of significant events. An ideal respiratory monitor should accurately and continuously detect airflow and have high reliability and tolerance to the sensor and a low rate of false-positive alarms, conditions that are not currently met by capnography, transthoracic impedance, or manual counting (5).

Masimo Corporation developed a noninvasive technology to monitor respiratory rate, which is integrated into Masimo pulse oximeters, called rainbow acoustic monitoring (RRa). RRa utilizes acoustic technology to detect vibratory sounds originating in the walls of the large airways during breathing and transforms the sounds into an electrical signal that is converted into a numerical measurement that corresponds to a respiration rate. Although preliminary investigations studied the accuracy of RRa in adults (6,7), it has not been evaluated in children. In this prospective, multicenter study, we evaluated the agreement of respiratory rate by RRa to capnography and compared capnography and RRa to the analysis of the recorded capnographic and RRa waveforms and breath sounds in children during postoperative care.

Methods

Following the approval of the Institutional Review Boards of each institution, and written parental permission and assent for patients 9 years of age and younger and consent of older pediatric patients, patients 12 months to 18 years of age were enrolled from three large urban academic medical centers: Cincinnati Children's Hospital, Cincinnati OH (CCHMC), Children's Medical Center, Dallas TX (CMC), and University of Arizona Medical Center, Tucson, AZ (UAZ), to monitor the respiratory status during the postanesthesia care unit (PACU) stay. Patients were excluded if they required intensive care after surgery, had tracheostomy or other mechanical airway devices, skin abnormalities at the planned site for the RRa sensor, nasal cannula or ECG electrodes, or had a known hypersensitivity to adhesive tape or monitor pads.


Figure 1 Acoustic respiratory rate sensor placed in a child's neck.

Upon enrollment in the study, demographic information (age, weight, height, and body mass index) was recorded. Patients were connected to a Pulse CO-Oximeter with rainbow® acoustic monitoring technology (Rad-87, version 7.7.0.6, 7.7.1.3, and 7.8.0.5) through an adhesive bio-acoustic sensor (RAS 125, revision C) and an adhesive, pediatric SpO2 finger sensor (LNCS Pdtx, Masimo, Irvine, CA, USA). Respiration rate monitoring by Pulse CO-Oximetry requires both an acoustic sensor and an optical SpO$_2$ sensor. The acoustic sensor was applied to the patient's neck according to the directions for use (Figure 1). Each patient was also fitted with a nasal cannula connected to a bedside capnography monitor (Capnostream 20, Oridion, Needham, MA, USA). Study capnography monitors underwent a periodic CO$_2$ calibration procedure per the manufacturer's directions for use, and data collected with capnography devices that were not within their calibration period were not included in the study. Waveforms of the acoustic monitor and capnography monitor were continuously recorded at 0.5 Hz by connection to a laptop computer with data collection software (ADC, Masimo) (Figure 2a). A subset of patients (the first 8 and 13 patients enrolled from 2 institutions) also wore thoracic impedance/electrocardiogram electrodes placed on the chest and connected to a bedside monitor (CAS 750, CasMed Inc., Branford, CT, USA). Respiration rate from the thoracic impedance monitor was collected every 2 min and recorded on the case report form along with simultaneous values from RRa and capnography. Recording of thoracic impedance/electrocardiogram was terminated after the 21 patients as a result of interpretable data due to poor signal quality from movement noise.

Data processing

Waveform files collected with the Rad-87 device were postprocessed to obtain respiration rate with the commercially released acoustic monitoring algorithm of the Rad-87 software. Respiration rates were also determined by retrospective analysis of the acoustic and capnographic waveform files and by listening to the recorded breathing sounds by the RRa (reference

(a)

(b)
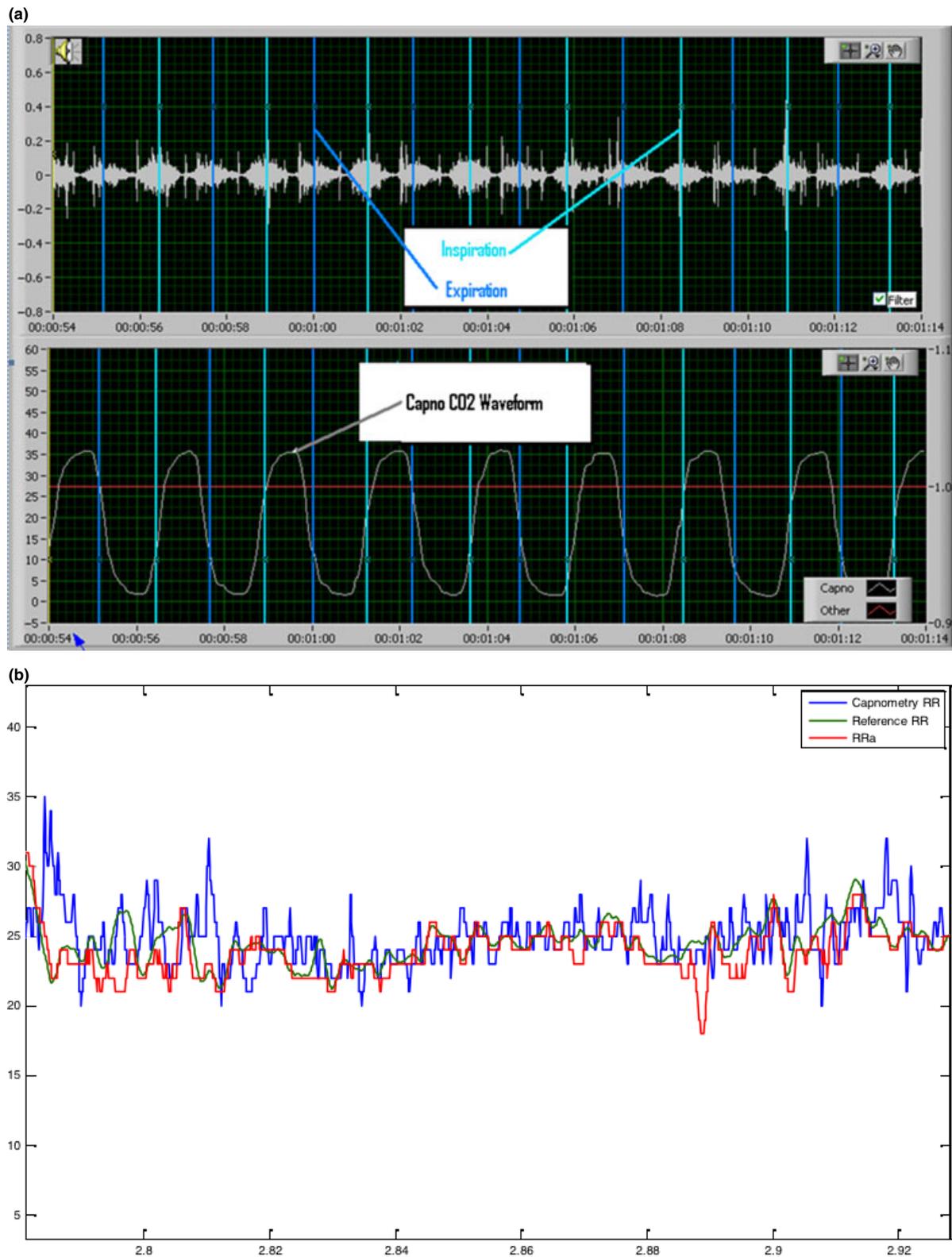
Figure 2 Simultaneous tracings of acoustic and capnography waveforms. (a) Notice the placement of the reference markers (inspiration and expiration). (b) Continuous waveform recording of acoustic monitoring, capnography, and by the analysis of waveform signal and sound recording data.

method). The reference method was developed because there is no accurate and reliable method of respiration rate measurement that can be used as a 'gold standard' reference method and has been described previously (7). Briefly, respiratory therapists and physicians contracted by Masimo Corporation used a software program (Tag-Editor, Masimo) for the simultaneous viewing of both the acoustic and capnography waveforms while listening to the breathing sounds from the acoustic signal to determine the placement of inspiration and expiration reference markers within the respiration cycle. A second examiner validated the reference markers. Any disagreements between the first and second examiner were reviewed and resolved by a third one. Another software program (Matlab 2007b, Mathworks Natick, MA, USA) was used to calculate the reference respiration rate from the reference markers. An example screenshot from the TagEditor program that shows the acoustic waveform, the capnography waveform, and reference markers is shown in Figure 2a. Continuous waveform recordings of capnography, RRa, and the analysis of waveform signal and sound recording data are shown in Figure 2b.

Data analysis

A sample size estimation was performed to allow detection of a bias of 1 b·min^{-1} for each test method when compared to the reference, assuming a standard deviation of 2 b·min^{-1}, resulting in a sample size of 34 subjects. Assuming a proportion of excluded subjects of 20%, we decided to enroll a minimum of 42 patients.

To assess tolerance for the nasal cannula and the acoustic sensor, the time that a patient removed either sensor from the start of the monitoring period was recorded. To determine reliability, defined as the percent monitoring time each device provided data, the amount of time each device displayed a respiration rate was divided by the total duration of monitoring time for which a reference value could be determined and expressed as a percentage with 95% confidence interval (CI).

The bias (difference between 2 different respiration rate measurement methods) and standard deviation (precision) for repeated measures were calculated and plotted with the upper and lower limits of agreement (±1.96 STDV) as described by Bland and Altman (8). Bland–Altman graphs were generated for the agreement in measurements obtained by RRa compared with

capnography and RRa and capnography compared with the automated reference method. The maximum width of the limits of agreement, which would not impair medical care, was set at ±5 b·min^{-1} based on an expected bias of around zero as was found in a previous study in adults (6).

Statistical significance of differences observed was determined by t-tests for normally distributed data or rank sum test for nonparametric data as appropriate. Single and multiple regression analyses were performed to determine the correlation of the test methods with various predictors such as age, gender, respiration rate, total monitoring time, and study site.

Results

Fifty-seven patients were enrolled between March 2011 and January 2012. Patients were recovering from a variety of surgical procedures such as ear myringotomy, nephrectomy, and internal fixation of bone fractures. The capnography devices used for data collection in 17 patients were found to be outside the calibration period, and consequently, these patients were removed from the analysis. Therefore, the three centers contributed 14 (UAZ), 16 (CCHMC), and 10 (CMC) patients for a total of 40 patients (Table 1, Figure 3). Patients were 55% male and had an average age of 7.4 years. Six patients removed the nasal cannula immediately after placement and would not permit replacement of the cannula and thus were not included in the assessment of accuracy. Thus, 34 patients were included in the data analysis for accuracy. A flowchart of included patients is shown in Figure 3. The weight range of the patients included in the accuracy analysis was between 10 and 50 kg with an average weight of 27.8 kg. Twenty of the 34 patients (59%) had a weight of less than 30 kg.

Six patients (15%) removed the nasal cannula immediately after placement and 9 more removed the nasal cannula prior to study completion; thus, 38% of patients (15 of 40 patients) demonstrated poor tolerance for the nasal cannula. The average age of patients who removed the nasal cannula (7.6 ± 4.5 year) was not significantly different ($P = 0.86$), from those who did not remove the cannula (7.9 ± 4.4 year). Only one of 40 patients removed the RRa sensor after 80 min.

Eighteen patients provided 142 data points collected from the thoracic impedance plethysmography—of
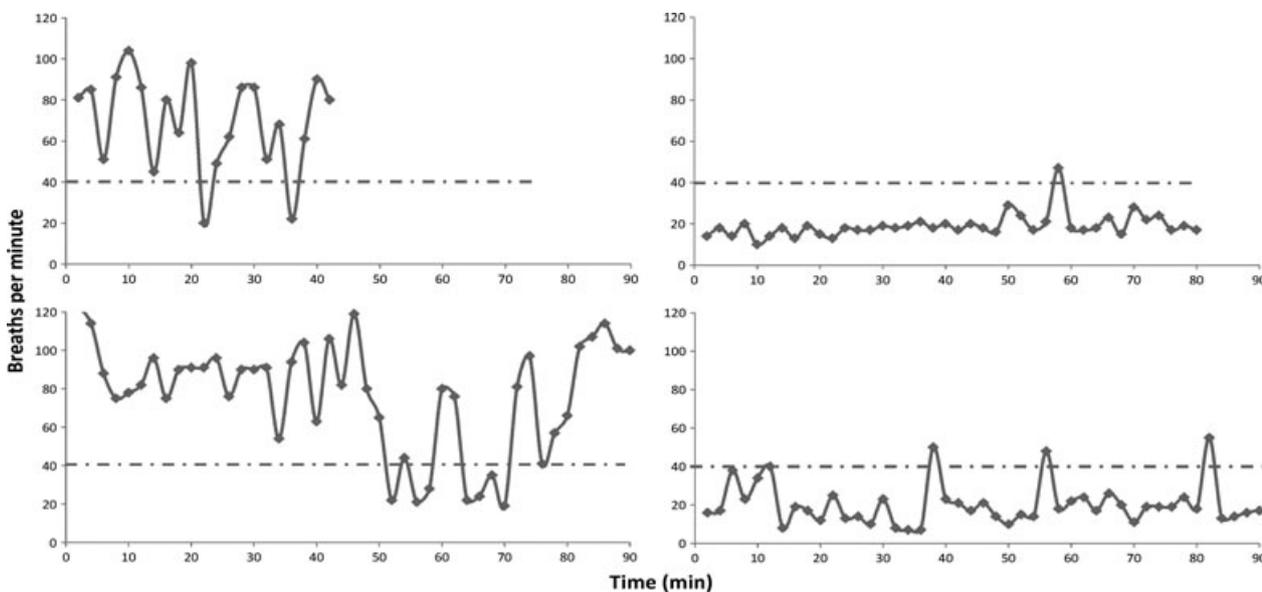
Table 1 Patient demographics for 40 pediatric postsurgical patients

	Age (year)	Weight (kg)	Height (m)	Body mass index (kg·m^2)	BMI-for-age percentile
Mean ± SD	7.4	27.8 ± 12.6	12.7 ± 3.0	16.3 ± 2.3	41.6 ± 29.8
Range	1.2–15	10–50	7.7–17.0	11.9–22.5	3–97

which 67 (47%) were outside of the measured respiratory rate range (>50 b·min^{-1}) and were considered erroneous. Figure 4 shows example cases of thoracic
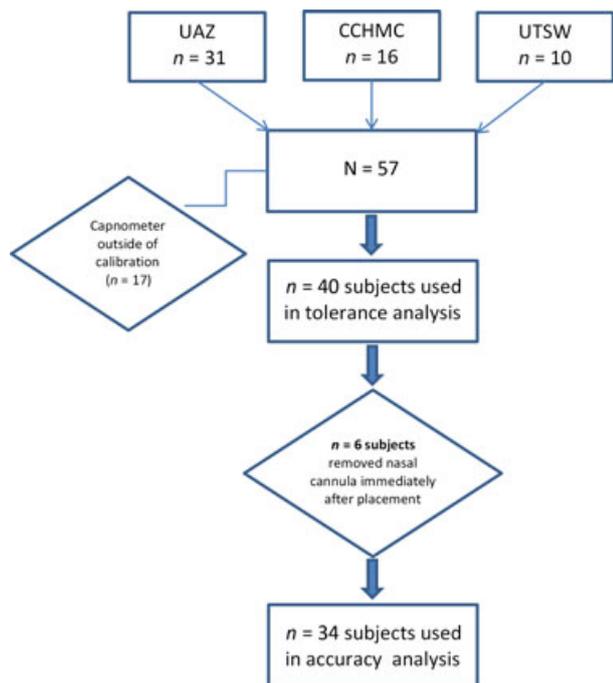
Figure 3 Flowchart for pediatric, postanesthesia care unit patients enrolled from University of Arizona Medical Center (UAZ), Cincinnati Children's Medical Center (CCHMC), and UT Southwestern Medical Center (UTSW).

impedance measurements taken every 2 min. Values above the dashed line (40 b·min^{-1}) were likely erroneous as they did not match the physiologic state and observations of the patient. Because of the high percentage of erroneous values, thoracic impedance plethysmography was not used for further comparisons.

The total duration of monitoring time for which a reference value could be determined was 2650 min (average 76 min) for capnography and 2849 min (average 83 min) for RRa. The reliability of capnography was 92% (95% CI 19.6% to 100%) of the total monitoring time and 90% (95% CI 22.8% to 100%) for RRa, a difference which was not significant ($P = 0.54$).

The bias and precision (± 1 SD) were -0.30 ± 3.5 b·min^{-1} for RRa compared with capnography and -0.1 ± 2.5 b·min^{-1} and 0.2 ± 3.4 b·min^{-1} for RRa and capnography compared with the automated reference method (Table 2). The difference in bias and precision between the two test methods was not statistically significant ($P = 0.41$).

Bland–Altman plots showed limits of agreement of -7.3 to 6.6 b·min^{-1} for RRa vs capnography (Figure 5a), -5.0 to $+5.0$ b·min^{-1} for RRa vs the automated reference method (Figure 5b), and -6.8 to $+6.7$ b·min^{-1} for capnography vs the automated reference method (Figure 5c). RRa had a large number of points outside the limits of agreement in the range of 25– 35 b·min^{-1}, while capnography had a large number of points outside the limits of agreement between 20 and 40 b·min^{-1}. Regression analysis for correlation of bias

Figure 4 Line plots showing intermittent measurements by thoracic impedance pneumography over time for four example patients with dashed line at 40 b·min^{-1}. Values greater than 40 b·min^{-1} were generally erroneous in that they did not correspond to clinical observation.

Table 2 Bias, standard deviation, and limits of agreement of acoustic monitoring (RRa) and capnometry compared with the reference method to determine respiratory rate for 34 pediatric postsurgical patients

Device	Mean ± sd b·min^{-1}	Number of Samples	Bias±SD (b·min^{-1})	Limits of agreement (b·min^{-1})
RRa	19.9 ± 6.3	85481	−0.1 ± 2.5	−5.0 to 5.0
Capnometry	19.9 ± 6.1	79528	0.2 ± 3.4	−6.7 to 6.9

with the respiration rate as measured by the reference method showed a significant but very weak correlation (coefficient of determination $R^2 = 0.03$, for RRa and 0.08 for capnography), indicating that respiration rate is only a very weak predictor of the respective test methods bias.

Multiple regression analysis including age, gender, test method respiration rate, total monitoring time, relative monitoring time (%), and study site showed no significant correlation between any of these predictors and the bias of either test method.

Discussion

Acoustic respiratory monitoring as developed by Masimo Inc. represents a different technology to determine respiratory rate than capnography or thoracic impedance, the currently used technologies in clinical care. Our study found that the acoustic technology displayed similar accuracy and reliability as capnography and better tolerance by children than capnography. Because there is no 'gold standard' for measurement of respiration rate, we compare acoustic monitoring (RRa) with two widely used methods with known limitations (capnography and thoracic impedance pneumography) and a novel reference method that combines listening to recorded breath sounds while observing the capnometry and acoustic waveforms. Impedance pneumography provided too erroneous to be included in the reference method or as a comparison method in this study. This study validates RRa by showing good agreement with capnography. Further, our study supports the analysis of waveform signal and sound recording data as a respiration rate reference method because respiration rate assessment by all three methods (acoustic monitoring, capnography and analysis of waveform signal, and sound recording data) shows good agreement. Compared to capnography with a nasal cannula, RRa displayed better tolerance in pediatric patients (only one of 40 patients removed the RRa sensor).

Mimoz's evaluation of RRa in adult patients using face mask capnography as reference found a close correlation between the two methods with a zero bias and limits of agreement of −1.4 to 1.4 b·min^{-1} (6). Our study found a similar bias and larger limits of agreement between RRa and capnography and for both RRa and capnography compared with the reference method. It is unclear whether the wider limits of agreement observed in our study were due to the pediatric patient population or the use of face mask (Mimoz study) vs nasal capnography. The bias and standard deviation of RRa compared with capnography and with the reference methods were not different depending on patient size, so the technology appears to perform similarly for all age/size groups.

Some patient activities affect RRa, such as talking, eating/drinking, and crying, and also affect capnography-derived respiration rate (9). The transient loss of data during these activities is not clinically relevant because they require the patient to be awake and breathing. A significant limitation of this study was that it was not designed to quantify the types of patient or environmental events that led to loss of data or inaccuracy by either RRa or capnography. A further systematic investigation of the types of environmental and pediatric patient activities that lead to inaccuracies and data drop out by capnography and RRa is required. Another limitation of this study is that we did not evaluate the sensitivity and specificity of either test method for detection of apneic events or respiratory depression. As one of the significant potential benefits of continuous respiration rate monitoring would be the detection of these events, further investigation is warranted. Also, we did not include children with weight less than 10 kg due to the sensor size and the small neck of these patients. Further studies are necessary in this population to determine the placement on other anatomic areas and define the accuracy in smaller pediatric patients. Lastly, we acknowledge that the reference method chosen for this study has not been validated for determination of respiration rate nor has it been used in clinical practice. However, it was recently utilized in an adult population study (7). We believe that this method of listening to a recorded acoustic signal while observing the acoustic and capnographic waveforms is equivalent to auscultation with a stethoscope, although, clearly, it does not replace direct patient observation along with auscultation at the bedside.
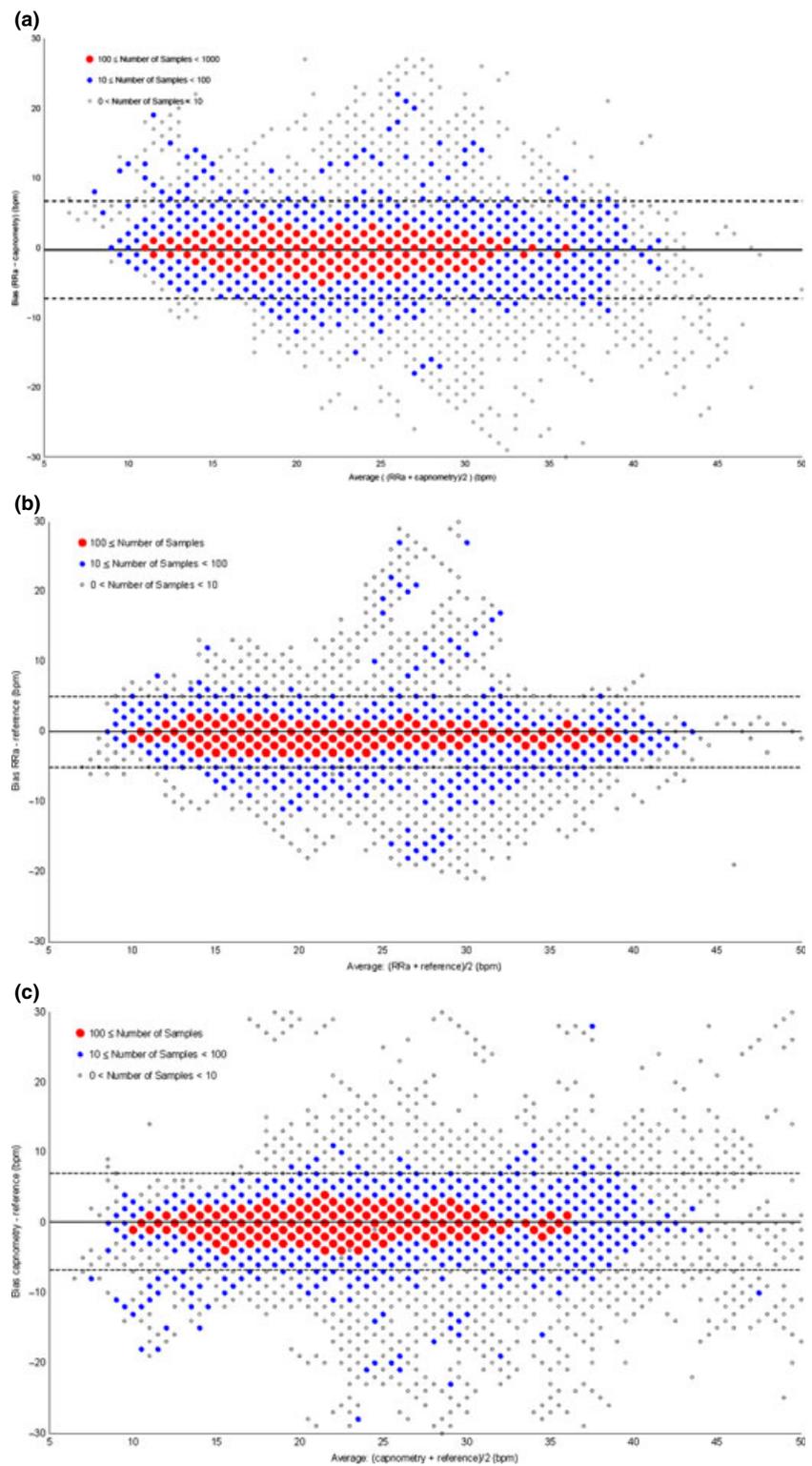
Figure 5 Bland–Altman plots for comparison of respiration rate by (a) acoustic monitoring (RRa) to capnography; (b) RRa to the respiratory rate obtained by the analysis of waveform signal and sound recording data; (c) capnography to the respiratory rate obtained by the analysis of waveform signal and sound recording data with the bias (solid line) and 95% limits of agreement (dashed lines), with red dots indicating greater than 100 data pairs, small blue dots indicating greater than 10 to 100 data pairs, and open circles indicating less than 10 data pairs.

Conclusions

Continuous respiration rate measurement from non-invasive, acoustic monitoring showed good agreement with nasal capnography, but was much better tolerated in postsurgical pediatric patients. Acoustic monitoring has the potential to increase the safety of pediatric patients by providing a reliable and

accurate method for the continuous monitoring of respiration rate.

Disclosures

Acknowledgments

Conflict of Interest

No conflicts of interest declared.

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