The Evaluation of a Noninvasive Respiratory Volume Monitor in Pediatric Patients Undergoing General Anesthesia

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BACKGROUND: Pediatric patients following surgery are at risk for respiratory compromise such as hypoventilation and hypoxemia depending on their age, comorbidities, and type of surgery. Quantitative measurement of ventilation in nonintubated infants/children is a difficult and inexact undertaking. Current respiratory assessment in nonintubated patients relies on oximetry data, respiratory rate (RR) monitors, and subjective clinical assessment, but there is no objective measure of respiratory parameters that could be utilized to predict early respiratory compromise. New advances in technology and digital signal processing have led to the development of an impedance-based respiratory volume monitor (RVM, ExSpiron, Respiratory Motion, Inc, Waltham, MA). The RVM has been shown to provide accurate real-time, continuous, noninvasive measurements of tidal volume (TV), minute ventilation (MV), and RR in adult patients.
In this prospective observational study, our primary aim was to determine whether the RVM accurately measures TV, RR, and MV in pediatric patients.
METHODS: A total of 72 pediatric patients (27 females, 45 males), ASA I to III, undergoing general anesthesia with endotracheal intubation were enrolled. After endotracheal intubation, continuous data of MV, TV, and RR were recorded from the RVM and an in-line monitoring spirometer (NM3 monitor, Phillips Healthcare). RVM and NM3 measurements of MV, TV, and RR were compared during a 10-minute period prior to the incision ("Presurgery") and a 10-minute period after the end of surgery ("Postsurgery"). Relative errors were calculated over 1-minute segment within each 10-minute period. Bias, precision, and accuracy were calculated using Bland-Altman analyses and paired-difference equivalence tests were performed.
RESULTS: Combined across the Presurgery and Postsurgery periods, the RVM's mean measurement bias (RVM − NM3 measurement) for MV was −3.8% (95% limits of agreement) (±1.96 SD): (−19.9% to 12.2%), for TV it was −4.9 (−21.0% to 11.3%), and for RR it was 1.1% (−4.1% to 6.2%). The mean measurement accuracies for MV, TV, and RR were 11.9%, 12.0%, and 4.2% (0.6 breaths/min), respectively. Note that lower accuracy numbers correspond to more accurate RVM measurements. The equivalence tests rejected the null hypothesis that the RVM and NM3 have different mean values and conclude with 90% power that the measurements of MV, TV, and RR from the RVM and NM3 are equivalent within ±10%.
CONCLUSIONS: Our data indicate acceptable agreement between RVM and NM3 measurements in pediatric mechanically-ventilated patients. Future studies assessing the capability of the RVM to detect respiratory compromise in other clinical settings are needed. (Anesth Analg 2017;XXX:00–00)

Respiratory complications in the postoperative period due to the residual effect of anesthetics, surgical trespass, and opioid administration continue to be a significant cause of adverse outcomes in pediatric patients.[1–4] Specifically, respiratory complications in the recovery room represent 9.2% of all perioperative complications in children, with the most common complications being bronchospasm, laryngospasm, and apnea.[3]

Respiratory assessment for nonintubated patients relies on oximetry, respiratory rate (RR), and clinical assessment of respiratory effort or distress.[5] Although multiple options to assess adequate respiration exist, they are qualitative and limited in their capability to objectively detect inadequate ventilation. No current noninvasive device used in children is capable of giving real time information such as tidal volume (TV) and minute ventilation (MV) for nonintubated patients.

Pulse oximetry is helpful in detecting oxygen desaturation episodes and improving safety in perioperative care. However, oxygen saturation is an indirect surrogate for ventilation as it represents a late indicator of poor ventilation especially in patients who are receiving supplemental oxygen.[6] While RR can be measured accurately by impedance from ECG leads, side stream capnography, or acoustic monitoring, RR alone is a poor indicator of respiratory status since it does not include information about the volume of the breaths or MV.[7–9] RR monitoring by side stream capnography has the additional limitation of poor compliance in children using nasal cannula or facemask. Monitoring

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end-tidal CO_2 ($ETCO_2$) using capnography has proved to be unreliable in nonintubated patients and provides a lagging indicator of respiratory status.[10–12]

New advances in technology and digital signal processing have led to the development of the impedance-based respiratory volume monitor (RVM, ExSpiron, Respiratory Motion, Inc, Waltham, MA). Although the RVM has been shown to provide objective real-time, continuous, noninvasive measurements of TV, MV, and RR in adults, this has not yet been validated in the pediatric population.[13,14]

The aim of this prospective observational study is to validate the capability of the RVM to accurately measure TV, MV, and RR in pediatric patients undergoing general anesthesia in the perioperative setting.

METHODS

This study was registered in ClinicalTrials.gov with an Identifier number of NCT02336022 on December 15, 2014, and Viviane Nasr is listed as the primary investigator. It adheres to the STROBE guidelines, and approved by the Institutional Review Board (IRB) at Boston Children's Hospital. Written parental consent was obtained as well as child assent when age appropriate during the preoperative period. Pediatric patients between the ages of 1 year and 17 years, ASA status I to III, and scheduled to undergo a surgical procedure under general anesthesia at Boston Children's Hospital were included. Patients undergoing an emergency procedure or procedures that would preclude the placement of the RVM leads, and patients with preexisting respiratory disease or respiratory muscular disease were excluded.

Experimental Design

Continuous respiratory data were collected simultaneously from an impedance-based RVM (ExSpiron, Respiratory Motion, Inc, Waltham, MA) and a monitoring spirometer placed in the respiratory circuit (NM3, Respironics NM3 Respiratory Profile Monitor, Philips Healthcare, Amsterdam, Netherlands). Both the RVM and NM3 provide real-time measurements of MV, TV, and RR.

Following induction of general anesthesia and intubation, the RVM electrode padset was placed in the recommended positions: sternal notch, xiphoid, and right mid-axillary line at the level of the xiphoid. At the beginning of each study, prior to surgical incision, approximately 1 minute of data was simultaneously collected on the RVM and NM3 devices, and the MV measured by the NM3 during this period was entered in the RVM to calibrate the RVM. For each patient, throughout the entire time the patient was intubated, continuous respiratory data were recorded from both the impedance-based RVM and the NM3 spirometer. Once the patient was extubated, RVM data collection continued, whenever possible, until the patient was discharged from the postoperative care unit (PACU).

Demographic information including age, weight, height, and type of the surgical procedure were recorded. In addition, the timing of the perioperative events such as intubation, surgical incision, desaturations, and extubation times were recorded for each patient.

Data and Statistical Analysis

RVM and NM3 measurements of MV, TV, and RR were compared using Bland-Altman analysis.[15] Specifically, two 10-minute periods of steady breathing without surgical manipulation were selected for comparison between the RVM and NM3 measurements for each patient. The first period was selected after RVM calibration and prior to the first incision ("Presurgery") and the second period was selected after the end of surgery and within 30 minutes prior to extubation while the patient was still under controlled mechanical ventilation ("Postsurgery"). The NM3 reports measurements of MV, TV, and RR for each breath, whereas the RVM reports measurements every 5 seconds. Each 10-minute period was subdivided into ten 1-minute segments over which RVM and NM3 measurements were averaged and compared. The relative errors (Bland-Altman) between the average RVM and NM3 values of MV, TV, and RR were calculated:[15]

$$\text{Error} = \frac{\text{RVM measurement} - \text{NM3 measurement}}{\frac{1}{2}\left(\text{RVM measurement} + \text{NM3 measurement}\right)}$$

Note that measurements were averaged over 1-minute segments to minimize cross-device measurement variability, mostly due to differences in measurement frequency (breath-to-breath versus 5 seconds) and potential time misalignment between the 2 devices.

Individual patient measurement bias was calculated as the average value of the relative errors over the Presurgery period, Postsurgery period, and Combined for each patient. Individual patient measurement accuracy was calculated as the square-root of the mean squared error over the Presurgery, Postsurgery, and Combined periods for each patient. Using this definition, lower accuracy numbers indicate better agreement between RVM and NM3 measurements. Individual patients' bias and accuracy were averaged over all patients to calculate the mean bias and accuracy.

Measurement precision was calculated using 2 methods, both accounting for within-patient and patient-to-patient measurement variability in a different manner, in order to validate the consistency of the data.

Method 1: Individual patient precision was calculated as the standard deviation of the 1-minute relative errors over the Presurgery, Postsurgery period, and Combined for each patient and then averaged over all patients.

Method 2: The precision across the entire population was calculated as the square root of the within-patient component of the mean squared error of a 1-way analysis of variance (ANOVA) on the individual (1 minute) relative errors, grouped by patient.

The 95% limits of agreement for MV, TV, and RR and their corresponding 97.5% confidence intervals were calculated using a method, which accounts for repeated measurements from each patient.[16] Following guidelines used by the US Food and Drug Administration (FDA) when assessing measuring agreement between devices, we defined the acceptable error for an individual patient to be less than 20%.

We performed paired-difference equivalence tests with null hypothesis that the 2 devices have different means and alternative hypotheses that the NM3 and RVM measurements of MV, TV, and RR are equivalent ($\delta = 0$) within an equivalence margin (B) of 10% relative error (ie, $B = \pm 0.10$). Specifically, 100(1 − 2α)% (95%) confidence intervals were estimated about the observed relative error means (ie, bias) for MV, TV, and RR:[17]

$$\left(\overline{y_1} - \overline{y_2}\right) \pm t_{(1-\alpha, 2(n-1))} \sqrt{s_P^2 \left(\frac{2}{n}\right)}$$

Here, $\left(\overline{y_1} - \overline{y_2}\right)$ is the relative error bias, n is the number of patients, t is the Student t inverse cumulative distribution function, and s_p is the standard deviation of the relative error (ie, precision). The test rejects the null hypothesis and favors the alternative hypothesis of equivalence if the interval falls entirely inside the equivalence interval (−10% to 10%).

As a secondary test of the measurement agreement (ie, bias) between devices, we performed 3 mixed-model ANOVAs with the difference between RVM and NM3 measurements (averaged over 1-minute periods) for either MV, TV, or RR as the response variable and random effects for patient and period (ie, Presurgery and Postsurgery). The null hypotheses were that the differences between the RVM and NM3 measurements were not different than zero. The goal of these tests was to demonstrate that RVM and NM3 were not systematically different across multiple patients, while accounting for repeated measures. One-way ANOVAs were performed to assess difference across age groups and across ranges of TV magnitude.

All data are presented as mean ± SEM unless otherwise indicated. All analyses were performed in Matlab 2014b (MathWorks, Natick, MA). Results were considered statistically significant at $P < .025$.

Sample Size Calculation

The population was divided into 3 separate patient subpopulations based on age according to the FDA's rule at 21 CFR 814.3 (s) (79 FR 1740, January 10, 2014): 1 year to less than 2 years; 2 years to less than 12 years; 12 years to less than 18 years.

We used the paired-difference equivalence test power formula to estimate the number of individual patients (N) necessary to demonstrate that the RVM and NM3 were equivalent with a margin of 10%:[18]

$$N = \frac{\left(z_\alpha + z_\beta\right)^2 \sigma^2}{\left(B - \delta\right)^2}.$$

Based on previous data in adults, the standard deviation of the relative error (σ) in MV, TV, and RR for an individual patient may be as high as 20%, a value that we use as a proxy for σ to be conservative. Assuming zero bias between the NM3 and RVM $(\delta = 0)$, we calculated that 24 patients were required to power the equivalence test at 90% ($z_\beta = 1.65$) with 5% chance of type I error ($z_\alpha = 1.96$). Since larger patient-to-patient variability between age and size groups was expected in the pediatric population compared to an adult population, the population was divided into 3 subpopulations, with 24 patients in each group.

RESULTS

Data from 72 patients (27 females/45 males, Table 1) who underwent a surgical procedure that required general anesthetic with endotracheal intubation were collected (Table 2) and were grouped into 3 subpopulations by age, with 24 patients in each age group. The mean bias, precision, and accuracy of MV, TV, and RR are summarized in Table 3 for Presurgery, Postsurgery, and Combined periods. The Presurgery and Postsurgery periods were selected while the patient was under controlled mechanical ventilation. Bias and accuracy are presented as averages across patients while precision is presented as both the mean across patients as well as the within-patient variability of the relative errors from all patients. Combined across the Presurgery and Postsurgery periods, the RVM's mean measurement bias (RVM − NM3 measurement) for MV was −3.8% (95% limits of agreement): (−19.9% to 12.2%), for TV was −4.9 (−21.0% to 11.3%), and for RR was 1.1% (−4.1% to 6.2%). The mean measurement accuracies for MV, TV, and RR were 11.9%, 12.0%, 4.2% (0.6 breaths/min), respectively, and the measurements' precisions of the RVM for MV, TV, and RR were 8.8%, 8.5%, and 3.4% (0.5 breaths/min), respectively.

In addition, we evaluated for systematic changes in MV and TV from Presurgery to Postsurgery. NM3 measurements of MV increased by 6.4% ± 4.2% from Presurgery to Postsurgery, while RVM measurements of MV decreased by 2.4% ± 3.9%, but these changes were not significant ($P > .21$, paired t test), suggesting that these observations are likely due to chance.

The accuracies of RVM's MV, TV, and RR measurements for each of the 3 subpopulations are compared in Figure 1. The mean accuracies were not significantly different across age groups ($P = .74$, .53, and .14 for MV, TV, and

Table 1. Patient Demographics and Subpopulations by Age

	Infants (1–2 y)	Children (2–12 y)	Adolescents (12–17 y)
Number of patients	24	24	24
Females, n (%)	9 (38)	6 (25)	12 (50)
Age, mean (SD), y	1.3 (0.2)	5.6 (2.4)	13.9 (1.8)
Weight, mean (SD), kg	10.4 (1.5)	22.7 (8.8)	52.6 (10.6)
Height, mean (SD), cm	78.2 (5.0)	116.1 (17.1)	160.7 (12.4)
BMI, mean (SD), kg/m^2	17.0 (1.1)	16.3 (1.9)	20.3 (2.9)
Procedure time, mean (SD), h	2.9 (1.7)	2.5 (1.3)	3.1 (1.6)

Abbreviation: BMI, body mass index.

Table 2. Surgical Procedures

Surgery Type	N
Urology (urethroplasty, ureteral reimplant, epispadias repair, hypospadias)	24
Orthopedic (closed reduction pinning, pao, hardware removal femur plate, osteotomy, open reduction internal fixation)	18
Ear, nose, eye: tympanomastoidectomy, septoplasty, tympanoplasty, otoplasty, cochlear implant	18
Upper/lower extremities (macrodactyly reconstruction, macrodactyly excision, transposition of finger, syndactyly release)	7
Hernia repair	3
Other	2

Abbreviation: pao, periacetabular osteotomy.

Table 3. Bias, Precision, and Accuracy of RVM During Pre- and Postsurgery Periods and Combined Across Both Periods

	Presurgery			Postsurgery			Combined		
	MV	TV	RR	MV	TV	RR	MV	TV	RR
Bias, mean (SEM), %	1.3 (0.7)	0.1 (0.7)	1.3 (0.3)	−7.6 (1.6)	−8.6 (1.7)	1.0 (0.4)	−3.8 (1.0)	−4.9 (1.0)	1.1 (0.3)
Precision, mean (SEM), %	4.4 (0.4)	3.8 (0.3)	2.4 (0.3)	5.5 (0.7)	5.3 (0.7)	3.2 (0.5)	8.8 (0.6)	8.5 (0.7)	3.4 (0.4)
Accuracy, mean (SEM), %	7.1 (0.5)	6.6 (0.5)	3.5 (0.3)	14.0 (1.1)	14.4 (1.2)	4.1 (0.5)	11.9 (0.8)	12.0 (0.8)	4.2 (0.4)
Within-patient component from repeated measures ANOVA, %	5.4	4.5	3.5	7.4	7.6	4.7	10.0	9.9	4.3

Abbreviations: MV, minute ventilation; RR, respiratory rate; TV, tidal volume.

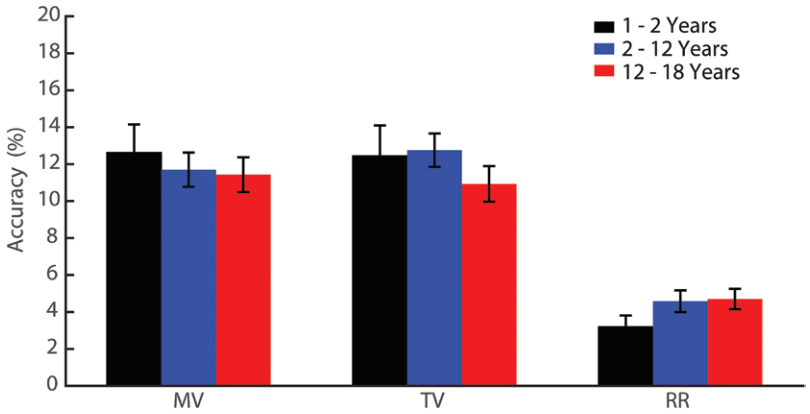

Figure 1. Mean (± SEM) accuracy of the RVM's MV, TV, and RR measurements grouped by patient age subpopulations. MV, TV, and RR accuracy were not significantly different across the three age ranges (1-way ANOVA, P = .74, .53, and .14 for MV, TV, and RR, respectively). Note that lower accuracies correspond to more accurate RVM measurements. ANOVA indicates analysis of variance; MV, minute ventilation; RR, respiratory rate; TV, tidal volume.

RR, respectively). Specifically, MV accuracies were 12.6% ± 1.5%, 11.7% ± 0.9%, and 11.4% ± 0.9% for groups 1 to 2 years old, 2 to 12 years old, 12 to 18 years old, respectively. Similarly, TV accuracies were 12.5% ± 1.6%, 12.8% ± 0.9%, and 10.9% ± 1.0% for groups 1 to 2 years old, 2 to 12 years old, 12 to 18 years old, respectively. RR accuracies were 3.2% ± 0.6% (0.7 ± 0.1 bpm), 4.6% ± 0.6% (0.7 ± 0.1 bpm), and 4.7% ± 0.5% (0.5 ± 0.1 bpm) for groups 1 to 2 years old, 2 to 12 years old, 12 to 18 years old, respectively.

Linear regressions showed that the accuracy of the MV and TV measurements were not related to the patient's height (P = .55, .33), weight (P = .44, .18), body mass index (P = .36, .18), or age (P = .61, .38).

Figure 2, A–C shows strong agreement between RVM and NM3 measurements of MV, TV, and RR, respectively, with 91.7% of all Presurgery and Postsurgery periods having less than 20% relative error indicated by dashed black lines. The difference of individual 1-minute measurements of MV, TV, and RR were computed and averaged separately over the Presurgery and Postsurgery periods for each patient. These differences are plotted against the best estimate of MV, TV, and RR (ie, the average of the RVM and NM3 measurement) in Figure 2, D–F, respectively. Each dot in Figure 2 represents a 1-minute measurement and each marker is the average over the 10 minutes Presurgery (closed symbols) or Postsurgery period (open symbols). The color and symbol corresponds to that patient's age subpopulation (black circle: 1–2 years, blue downward-pointing triangle: 2–12 years, red upper-pointing triangle: 12–18 years). Note that MV and TV tend to increase with patient age, while RR tends to decrease. The middle dashed lines represent the average biases (–0.0.082 L/min, –7.8 mL, and 0.12 min^{-1}, for MV, TV, and RR, respectively) and the upper and lower dashed lines are the 95% limits of agreement and their corresponding 97.5% confidence intervals shaded gray. Specifically, the 95% limits of agreement for MV were −0.76 (97.5% CI, −0.85 to −0.67) L/min to 0.60 (97.5% CI, 0.51 to 0.68) L/min. The 95% limits of agreement for TV were −60.4 mL (97.5% CI, −67.1 to −53.7) to 44.8 mL (97.5% CI, 38.1 to 51.5). For RR, the 95% limits of agreement were −1.45 bpm (97.5% CI, −1.58 to −1.32) to 1.68 bpm (97.5% CI, 1.55 to 1.81). As expected, the spread of measurement error of MV and TV increases with larger MV and TV, while the error in RR is independent of magnitude.

The equivalence tests rejected the null hypothesis that the RVM and NM3 have different mean values of MV, TV, and RR and therefore accepts the alternative hypothesis of equivalence. The 95% confidence intervals of the relative errors were for MV (–7.4% to –0.2%), TV (–8.4% to –1.3%), and RR (–0.48% to 2.6%). Since these confidence intervals are completely contained within the equivalence margin of (–10% to 10%), the tests conclude with 90% power that the measurements of MV, TV, and RR from the RVM and NM3 are equivalent within ±10%. The associated 1-sided t tests used have $P < .0001$.

Furthermore, 3 separate mixed-model ANOVAs with patient and period as random effects failed to reject the null hypotheses that NM3 and RVM measurements of MV, TV, and RR were equal (P = .46, .27, and .24 for MV, TV, and RR, respectively).

To explore the RVM's ability to accurately measure respiratory parameters across the range of TV magnitudes, individual 1-minute measurements of MV, TV, and RR were grouped into 3 ranges: 20 to 100 mL, 100 to 300 mL, and 300 to 602 mL. The accuracy for each patient within each range of TV was calculated. Figure 3 depicts this stratification average across the population and reveals that the RVM accuracy is less than 15% across all TV ranges. MV and TV accuracies

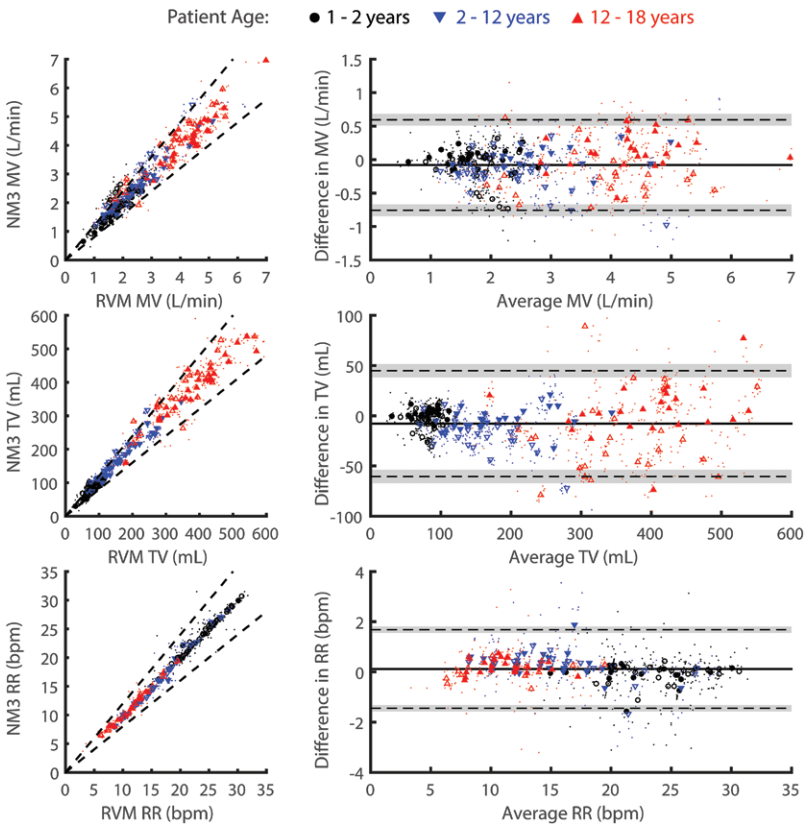

Figure 2. Measurement error analysis for 72 pediatric patients. A–C, Correlation plots between NM3 and RVM measurements of MV (A), TV (B), and RR (C). Dots represent 1-minute measurements and larger marker represents the average measurement over 10-minute Presurgery (closed symbols) and Postsurgery (open symbols) periods. 91.7%, 91.0%, and 100% of all periods are within the 20% relative error bounds (dashed lines) for MV, TV, and RR, respectively. D–F, Bland-Altman measurement error analysis from 10-minute Presurgery and Postsurgery periods of the procedure. Dots represent 1-minute measurements and larger markers represent patient average measurements over 10-minute Presurgery (closed symbols) and Postsurgery (open symbols) periods. x-axis: average measurement of RVM and NM3. y-axis: difference between RVM and NM3 of MV (D), TV (E), and RR (F). Middle dashed line: average difference (MV: L/min, TV: mL, RR: bpm). Upper and lower dashed lines: 95% limits of agreement and their corresponding 97.5% confidence intervals shaded gray. Color and symbols correspond to patient age subpopulation (black circles: 1–2 years, blue downward-pointing triangle: 2–12 years, red upward-pointing triangle: 12–18 years). MV indicates minute ventilation; RR, respiratory rate; RVM, respiratory volume monitor; TV, tidal volume.

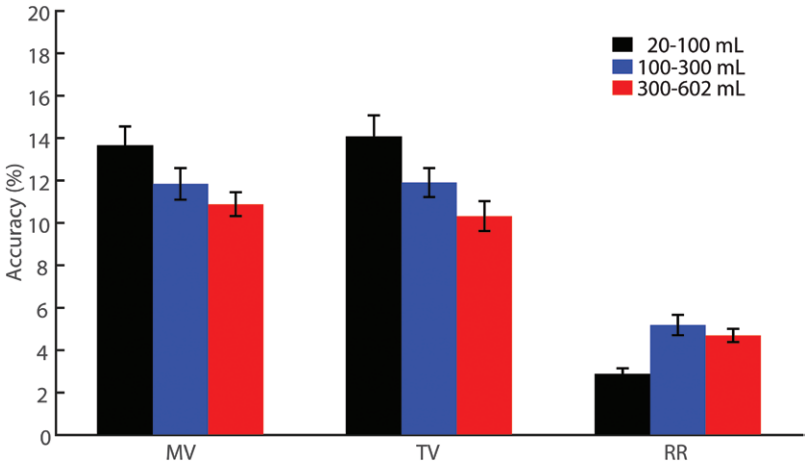

Figure 3. Stratification of MV, TV, and RR accuracy according to magnitude of TV (black: 20–100 mL, blue: 100–300 mL, red: 300–602 mL). Individual 1-minute measurements were grouped by TV magnitude and the accuracies for each patient within each TV range were calculated. Bars are the mean (± SEM) accuracy across the population. MV and TV accuracy were not significantly different across the 3 TV ranges (1-way ANOVA, $P = .28$, $P = .14$, respectively). Note that lower accuracies correspond to more accurate RVM measurements. ANOVA indicates analysis of variance; MV, minute ventilation; RR, respiratory rate; RVM, respiratory volume monitor; TV, tidal volume.

were not significantly different across the 3 TV ranges ($P = .28$, $P = .14$, respectively). Table 4 lists the mean MV, TV, and RR measurements within each TV range and the MV, TV, and RR accuracies in terms of real units for each range.

DISCUSSION

Our study demonstrates that the noninvasive RVM used in this study can measure TV, MV, and RR with clinically relevant accuracy and precision in intubated mechanically ventilated pediatric patients under general anesthesia. Although the RVM has been validated and used in adults in different clinical scenarios, this is the first pediatric validation study for the ExSpiron RVM.[9,12–14,19–23]

In children, respiratory complications are the most common adverse events during the postoperative period.[1–4,24] Hypoxemia after surgery is common, with 38% of patients having at least one contiguous desaturation lasting at least 1 hour. Unfortunately, 90% of these episodes are missed with the current available technologies.[25] In addition, there is no current objective way to assess ventilation in nonintubated pediatric patients in the immediate postextubation period in the PACU. Our current respiratory monitoring in children is based on pulse oximetry, capnography, RR, and clinical observation. Pulse oximetry may provide inaccurate measurements with body movement and in certain settings such as decreased perfusion, hemoglobinopathies, and

Table 4. Mean MV, TV, and RR Accuracy of the RVM Stratified by TV Magnitude

	23–100		100–300		300–602	
TV Range, mL	**Mean**	**Accuracy**	**Mean**	**Accuracy**	**Mean**	**Accuracy**
MV, mL/min	1718	242	2670	301	4395	410
TV, mL	76.4	10.8	181.4	22.4	407.8	39.3
RR, min^{-1}	22.9	0.6	15.4	0.8	10.8	0.5

Abbreviations: MV, minute ventilation; RR, respiratory rate; RVM, respiratory volume monitor; TV, tidal volume.

color interferences. Furthermore, oxygen desaturation is a late indicator of respiratory decline and does not provide information about adequacy of ventilation. Capnography, in contrast, assesses respiration via measurement of expired CO_2 ($ETCO_2$) that may be unreliable due to inadequacies of sampling and patient's compliance, especially in pediatric nonintubated, nonsedated patients.[10,11]

In addition, a recent analysis from the Pediatric Sedation Research Consortium reports the most common adverse events during pediatric sedation/anesthesia outside the operating room were related to respiratory problems. Specifically, oxygen desaturation occurs 157 times per 10,000 sedations, stridor and laryngospasm both occur in 4.3 per 10,000 sedations, and apnea had a frequency of 24 per 10,000 encounters.[26] Therefore, the frequency of respiratory depression and the lack of objective respiratory assessment emphasize the need for an accurate continuous respiratory monitor in the perioperative/procedural settings.

In this study, desaturations were recorded in the PACU in 3 patients. These desaturation events were preceded by a decrease in MV in each case, suggesting that similarly to what has been reported in adults, the RVM may provide an earlier indication of respiratory compromise than pulse oximeter in the pediatric population.[23] However, future studies are needed to evaluate the utility of RVM in a variety of pediatric settings such as nonintubated patients, sedated patients, postoperative patients, or those with obstructive breathing caused by opioids as has been previously shown in adults.[13,19]

Limitations of our study include the lack of analysis during the periods of surgical interference because we did not analyze the data when electrocautery was used and when excessive surgical manipulation occurred. The relative errors between RVM and NM3 measurements of MV, TV, and RR were estimated using average values calculated over 1-minute segments in order to compensate for cross-device measurement noise and time misalignment. This provided less granularity to the data, but compensated for any potential time misalignment. Another limitation, as discussed above, is that the accuracy of the RVM device in this study was primarily quantified in intubated patients receiving positive pressure ventilation. However, this device has been validated in both controlled and spontaneously breathing adults and there are no data that would suggest that the impedance would be different between controlled and spontaneously ventilated pediatric patients.[14,19] Therefore, the clinical usefulness of the device in nonintubated patients is promising. Lastly, the RVM was calibrated using the NM3 at the beginning of the study for each patient to optimize its accuracy. The RVM can be calibrated using any FDA-approved spirometer or ventilator. The calibration step might be difficult to perform in the postoperative environment, where some loss in accuracy might be accepted in favor of streamlining the process.

In conclusion, this novel noninvasive respiratory monitoring device is now validated in mechanically ventilated pediatric patients. Future prospective studies assessing the applicability of the RVM device in the clinical setting to detect respiratory compromise are needed. Providing accurate and real-time measurements of MV, TV, and RR may allow clinicians and health care providers to intervene in a timely manner and prevent respiratory-related adverse outcomes.

DISCLOSURES

Name: Andrea D. Gomez-Morad, MD.
Contribution: This author helped design the study, collect the data, and write the manuscript.
Conflicts of Interest: None.
Name: Joseph P. Cravero, MD.
Contribution: This author helped design the study, review the data analysis, and write the manuscript.
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Name: Brian C. Harvey, PhD.
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Conflicts of Interest: Dr Brian C. Harvey works for Respiratory Motion, Inc, and has equity interest in Respiratory Motion, Inc.
Name: Rachel Bernier, MPH.
Contribution: This author helped design the study, recruit the patients, and write and revise the manuscript.
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Contribution: This author helped design the study, review the data analysis, and write and revise the manuscript.
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