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Original Contribution

Improving patient safety during procedural sedation via respiratory volume monitoring: A randomized controlled trial☆

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ABSTRACT

Study objective: Assess the utility of a respiratory volume monitor (RVM) to reduce the incidence of low minute ventilation events in procedural sedation.
Design: Randomized control trial
Setting: Endoscopy suite
Patients: Seventy-three total patients (ASA Physical Status 1–3) undergoing upper endoscopies were analyzed.
Intervention: Patients were randomized into two groups using a computer generated randomization table: Control ($n = 41$): anesthesia provider was unable to see the screen of the RVM; RVM ($n = 32$): anesthesia provider had access to RVM data to assist with management of the case.
Measurements: Minute ventilation (MV), tidal volume, and respiratory rate were continuously recorded by the RVM. MV is presented as percent of Baseline MV ($MV_{Baseline}$), defined during a 30s period of quiet breathing prior to sedation. We defined Low MV as MV < 40% $MV_{Baseline}$, and calculated the percentage of procedure spent with Low MV. Patients in the RVM group were stratified based on whether the anesthesiologist rated the RVM as "not useful", "somewhat useful", or "very useful" during the case.
Main results: Control patients experienced twice as much Low MV compared to RVM patients (15.3 ± 2.8% vs. 7.1 ± 1.4%, $P = 0.020$). The "not useful" (13.7 ± 3.8%) group showed no improvement over the Control group ($p = 0.81$). However, both the "very useful" (4.7 ± 1.4%) and "somewhat useful" (4.9 ± 1.7%) groups showed significant improvement over the "not useful" group ($p < 0.05$).
Conclusions: Patients in the Control group spent more than double the amount of time with Low MV compared to the RVM group. This difference became more pronounced when the anesthesiologist found the RVM useful for managing care, lending credibility to the usage of minute ventilation monitoring in procedural sedation.

1. Introduction

In the fast-paced procedural sedation environment, patients are at risk for respiratory depression due to decreased respiratory drive and loss of muscle tone in the upper airway muscles [1–5]. ASA guidelines state that ventilation should be continuously monitoring during sedation [6], but current respiratory monitors have been insufficient at quantitatively measuring respiratory status. While pulse oximetry is commonly used, it provides a late indication of respiratory depression, especially with the administration of supplemental oxygen [7,8]. Capnography has unfortunately proven to be unreliable in non-intubated patients because of issues of patient non-compliance, patient movement artifacts, and difficulty of interpreting the CO_2 waveforms [9–13]. Monitoring respiratory status in upper endoscopies can be especially difficult because oral instrumentation further compromises capnography cannula positioning. Airway obstruction can be exacerbated by the endoscope, and repositioning to address questionable airway obstruction or respiratory depression can be difficult without interfering with the procedure underway.

A recently developed non-invasive respiratory volume monitor (RVM) (ExSpiron, Respiratory Motion, Inc., Waltham, MA) provides continuous measurements of minute ventilation (MV), tidal volume (TV), and respiratory rate (RR). The RVM has better than 90% accuracy for MV and TV and 98% accuracy for RR in both intubated and non-intubated patients [14,15]. During procedural sedation, the RVM detects

☆ **Disclosures**: Respiratory Motion provided the respiratory volume monitors for this study.

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the decrease in MV and also identifies increases following airway maneuvers such as chin lifts and jaw thrusts [16,17].

In this randomized control trial, continuous respiratory metrics were collected in upper endoscopy patients and the incidence of respiratory depression was quantified. We randomized whether the anesthesiologist managing the case had access to continuous RVM metrics and examined the consequent effects on the patients' respiratory status. We hypothesized that the use of the RVM by the anesthesiologist would result in a decrease in the incidence of respiratory depression in patients under procedural sedation.

2. Materials and methods

2.1. Patients

This parallel-group randomized control trial was approved by the Fletcher Allen Healthcare (renamed University of Vermont Medical Center) Institutional Review Board, and all patients provided written informed consent prior to enrollment. The study was registered at ClinicalTrials.gov (NCT02310230) and followed the CONSORT guidelines [18]. Inclusion criteria included patients scheduled to undergo upper gastrointestinal endoscopy with anesthesiologist-administered sedation, age >21. Exclusion criteria included history of thoracotomy, history of chronic obstructive pulmonary disease, body mass index (BMI) >43. Patients scheduled for a screening upper endoscopy without associated procedures were also excluded, as the duration is usually quite short. Patients were randomly assigned into one of two groups by a computer generated randomization table. In the Control group, the anesthesia provider was unable to see the screen of the RVM. In the RVM group, the anesthesia provider had access to RVM metrics (MV, TV, and RR) displayed on the screen to assist with management of the case.

2.2. Instrumentation

Continuous respiratory metrics were collected via a bio-impedance RVM (ExSpiron, Respiratory Motion, Inc., Waltham, MA) with an attached electrode PadSet spanning the thoracic region. The electrodes were placed in the recommend positions at the sternal notch, xiphoid, and mid-axillary line at the level of the xiphoid. For patients in the Control group, routine monitoring and care were used (oxygen saturation monitoring, blood pressure, heart rate, capnography), and the anesthesia and care team were blinded to RVM measurements. For RVM group patients, RVM metrics of MV, TV, and RR were available in addition to standard monitoring.

2.3. Study procedure

Following patient consent, the PadSet was placed and attached to the monitor. MV, TV, and RR data were continuously acquired from pre-procedure holding until the subject was eligible for discharge from the post-procedure recovery area. Before sedation and once the subject was positioned for their procedure, a thirty-second baseline representative of quiet, normal breathing was taken by the RVM. The average MV from this period was defined as 100% $MV_{Baseline}$. Patients were sedated by anesthesia staff with propofol infusions and boluses, with or without other agents (ketamine, fentanyl, and midazolam). A research assistant recorded the timing and doses of sedating agents throughout the procedure, as well as any airway maneuvers (i.e., chin lift, jaw thrust) and subject positioning changes performed by the care team. For patients in the RVM group, the anesthesia provider was instructed on how to interpret the displayed respiratory trace, MV, TV, and RR and was encouraged to use the RVM to direct care. In the RVM group, the anesthesia provider used a Likert-like scale to assign a rating at the end of the case based on how useful they found the RVM for management of their patient's anesthesia and airway. The rating was on a scale from 1 ("not-useful") through 5 ("very-useful").

2.4. Data analysis

We assessed the respiratory status of patients as $\%MV_{Baseline}$, and defined MV < 40% $MV_{Baseline}$ as Low MV (i.e., potentially unsafe respiratory depression), mirroring the ARDSnet definition of insufficient ventilation for extubation [19]. We calculated the percentage of each patient's case that was spent with Low MV. Total intra-operative propofol was normalized by patient body weight and procedure length. Two-sided *t*-tests were performed to compare procedure times, propofol administered, number of airway maneuvers, mean % $MV_{Baseline}$ throughout the procedure, and percent of procedure with Low MV across Control and RVM groups.

To examine the effects of varying anesthesiologist engagement with the RVM, we further subdivided the RVM group by survey score (1–2: "Not Useful", 3–4: "Somewhat Useful", 5: "Very Useful"). One-way ANOVAs were performed to compare the percentage of procedure with Low MV, procedure time, medication administered, and average airway maneuvers among these subgroups.

Preliminary data indicated patients under standard of care spent approximately 15% of the procedure time below 40% of their $MV_{Baseline}$, with a standard deviation of 10%. We estimated at least 28 patients were needed in each group to detect if the Control group spent half this amount of time with low MV (i.e., 7.5%) [20].

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 $P < 0.05$.

3. Results

One-hundred patients (50 Control/50 RVM) were recruited for this study between September 22, 2014 and May 9, 2016. Twenty-seven patients (9 Control/18 RVM) were excluded. Therefore, a total of 73 patients (41 Control/32 RVM) were analyzed (Table 1). Patients were excluded for the following reasons: anesthetics administered prior to baseline MV measurement (4 Control/8 RVM), technical issues (3/3), sedation administered by gastroenterologist (1/0), intubation or general anesthesia (1/4), incorrect monitor setup (0/2), and case cancellation (0/1).

Patients underwent endoscopic ultrasound (EUS, 45 patients), endoscopic retrograde cholangiopancreatography (ERCP, 22 patients), or a hybrid procedure (EUS + ERCP, 6 patients).

3.1. Control vs. RVM group comparison

Patients in Control group (41 patients) and RVM group (32 patients) had similar anthropometrics, procedure lengths, and were administered similar amounts of intra-operative propofol (Table 1).

Respiratory data from representative patients in the Control and RVM groups are displayed in Figs. 1 and 2, respectively. The patient in the Control group (Fig. 1) received 527 mg of propofol and 47 mg of ketamine and spent 20.9% of the procedure under 40% $MV_{Baseline}$. The patient experienced an extended period of time after 11:20 following the final dose of propofol and ketamine. The patient in the RVM group (Fig. 2) received 527 mg of propofol and 10 mg of ketamine and spent 3.8% of the procedure under 40% $MV_{Baseline}$. The anesthesia provider ceased boluses of propofol and ketamine after the patient drops below 40% $MV_{Baseline}$ for as at 10:09 which allowed the patient to recover.

Control group patients spent more than twice the amount of procedure time with Low MV compared to the RVM group (15.3 ± 2.8% vs. 7.1 ± 1.4%, $p = 0.020$, Fig. 3A). The percent of procedure time with Low MV ranged from 0 to 68.8% for the Control group compared to 0–30.8% for the entire RVM group. Furthermore, more Control group patients spent extended periods of time at a Low MV. Specifically, 8/41

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Table 1
Patient cohort anthropometrics, procedure details, and respiratory metrics.

Anthropometrics	Population	Control	RVM	*p*-Value
Number of patients	73	41	32	
Males/females	34/39	18/23	16/16	
Procedure (EUS/ERCP/EUS + ERCP)	45/22/6	23/15/3	22/7/3	
Age (SD), years	56.2 (15.2)	52.9 (17.0)	60.5 (11.0)	0.033
Weight (SD), kg	79.1 (21.4)	82.1 (23.8)	75.3 (17.1)	0.183
Height (SD), cm	169.4 (10.8)	169.5 (9.7)	169.3 (12.0)	0.929
BMI (SD), kg/m^2	27.4 (6.2)	28.3 (6.9)	26.2 (5.0)	0.147
ASA physical status (1/2/3)	2/45/26	2/24/15	0/21/11	0.845
Length of procedure (SD), min	33.2 (1.8)	30.1 (1.9)	37.2 (3.2)	0.050
Intra-Op propofol (SEM), mcg/kg/min	240.4 (12.9)	239.7 (16.9)	241.4 (19.9)	0.947
Intra-Op midazolam (SEM), mcg/kg/min	0.51 (0.09)	0.59 (0.11)	0.41 (0.14)	0.302
Intra-Op fentanyl (SEM), ng/kg/min	4.0 (1.4)	3.5 (2.0)	4.7 (1.8)	0.657
Intra-Op ketamine (SEM), mcg/kg/min	8.2 (1.0)	7.5 (1.5)	9.0 (1.3)	0.445
Average MV (SEM), % of $MV_{Baseline}$	96.8 (5.4)	86.7 (5.9)	109.8 (9.3)	0.034
Time with low MV (SEM), % of procedure	11.7 (1.8)	15.3 (2.8)	7.1 (1.4)	0.020
Number of airway maneuvers (Range)	2.2 (0–8)	2.2 (0–7)	2.3 (0–8)	0.831

EUS: endoscopic ultrasound; endoscopic retrograde cholangiopancreatography; EUS + ERCP: hybrid EUS and ERCP.

(20%) of Control patients spending >25% of their procedure with Low MV compared to 2/32 (6%) of RVM patients. Three Control patients spent >50% of their procedure with Low MV while no RVM patients spent >50% with Low MV. Control group patients also had a significantly lower average MV during the procedure compared to the RVM group patients (86.7 vs. 109.8% $MV_{Baseline}$, $p = 0.034$).

3.2. RVM group subdivided by survey score

The RVM group was further subdivided into groups based on the anesthesiologist survey score, with a rating from 1 to 5 assigned for how useful the anesthesiologist found the RVM for management of the patient's airway and anesthesia. Specifically, patients were divided into three groups: ("Not Useful": 1/5 or 2/5, $n = 8$; "Somewhat Useful": 3/5 or 4/5, $n = 12$; "Very Useful": 5/5, $n = 12$). The three subgroups had similar ages, weights, heights, BMI, procedure lengths, received similar amounts of propofol, and had similar numbers of airway maneuvers performed ($p > 0.087$, 1-way ANOVAs).

Patients whose anesthesiologist found the RVM "somewhat useful" (12/32) or "very useful" (12/32) spent significantly less of their procedure with Low MV compared to patients whose anesthesiologist found the RVM "not useful" (8/32, $p = 0.039$ and $p = 0.035$, respectively). Specifically, patients in the "somewhat useful" and "very useful" groups spent 4.9 ± 1.7% and 4.7 ± 1.4% of their procedure with Low MV, respectively, while patients in the "not useful" group spent 13.7 ± 3.8% of their procedure with Low MV (Fig. 3B). Patients in the "not useful" group spent a similar amount of time with Low MV as the Control group ($p = 0.81$).

4. Discussion

This randomized control trial tested whether the use of a Respiratory Volume Monitor can lead to a decrease in the incidence of respiratory

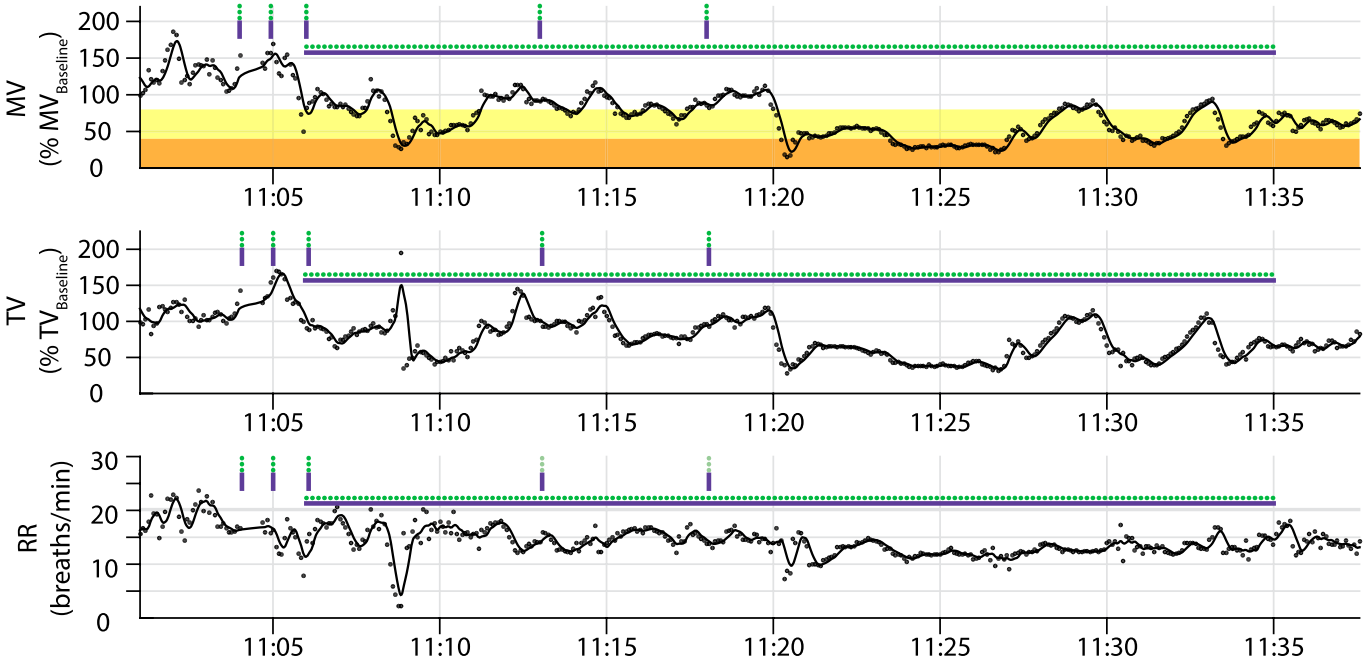

Fig. 1. Respiratory data for a representative patient undergoing an endoscopic ultrasound in the Control group where the anesthesia provided was blinded to Respiratory Volume Monitor. Minute Ventilation (MV, top) and Tidal Volume (TV, middle) are presented as percent of baseline and Respiratory Rate (RR, bottom) is in breaths per minute (bpm). Timing of propofol (green, dotted lines) and ketamine (purple, solid lines) administration are denoted by vertical (boluses) and horizontal (infusions) lines. The patient received a total of 527 mg of propofol and spent 20.9% of the procedure under 40% $MV_{Baseline}$ (orange shaded region). (For interpretation of the references to colour in this figure legend, the reader is referred to the web version of this article.)

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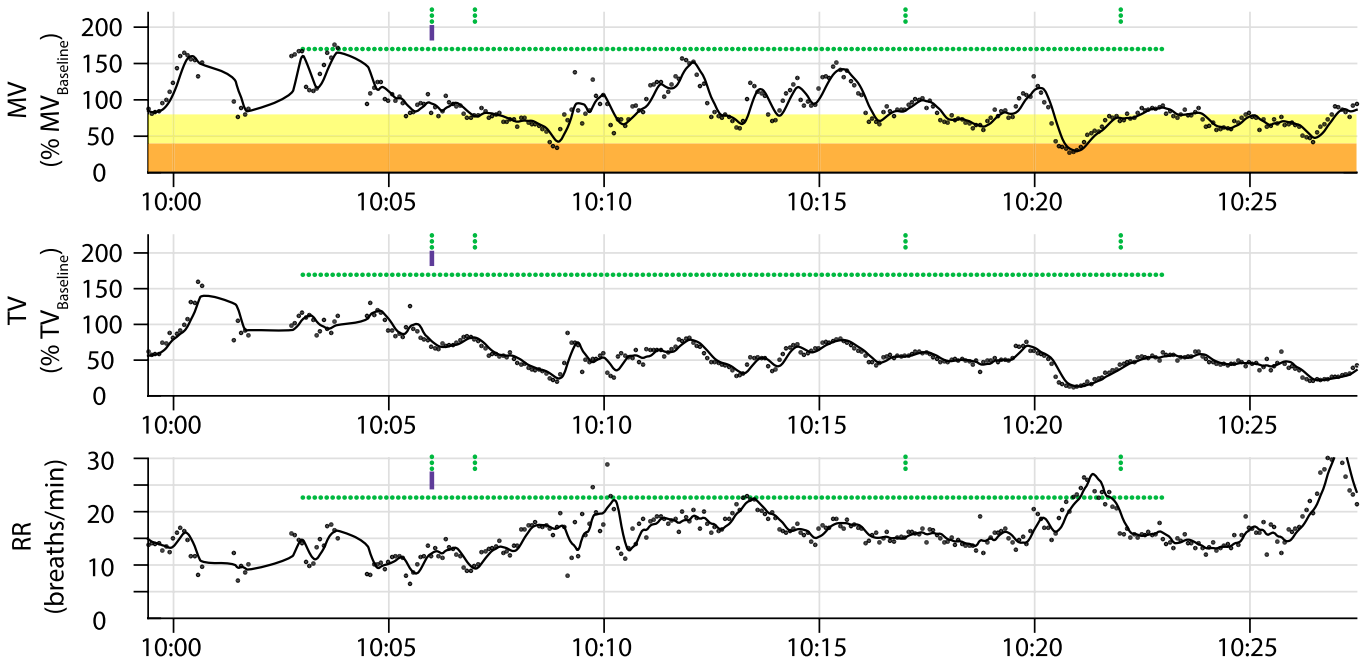

Fig. 2. Respiratory data for a representative patient undergoing an endoscopic ultrasound in the RVM group where the anesthesia provided was encouraged to use the Respiratory Volume Monitor to direct care. Minute Ventilation (MV, top) and Tidal Volume (TV, middle) are presented as percent of baseline and Respiratory Rate (RR, bottom) is in breaths per minute (bpm). Timing of propofol (green, dotted lines) and ketamine (purple, solid lines) administration are denoted by vertical (boluses) and horizontal (infusions) lines. The patient received a total of 701 mg of propofol and spent 3.8% of the procedure under 40% $MV_{Baseline}$. (For interpretation of the references to colour in this figure legend, the reader is referred to the web version of this article.)

depression in patients undergoing complex upper endoscopy under procedural sedation. We found that patients in the RVM group, in which anesthesia providers used the RVM to direct care, spent half the amount of time spent with potentially unsafe minute ventilation when compared to those in the Control group (15.3% vs. 7.1%, Fig. 3A). Seventy-five percent of anesthesiologists in the RVM group (24/32) found the RVM "somewhat useful" or "very useful". Patients whose anesthesiologists found the RVM "useful" benefited from a 64% reduction in time with Low MV compared to patients of anesthesiologists who considered the device "not useful" (13.7 vs. 4.8%, Fig. 3B). Our data does not show why directing care using real-time feedback from the RVM results in less depressed ventilation. Perhaps monitoring allowed the anesthesiologists to better titrate sedatives, analgesics, and anesthetics, although propofol administration was similar between

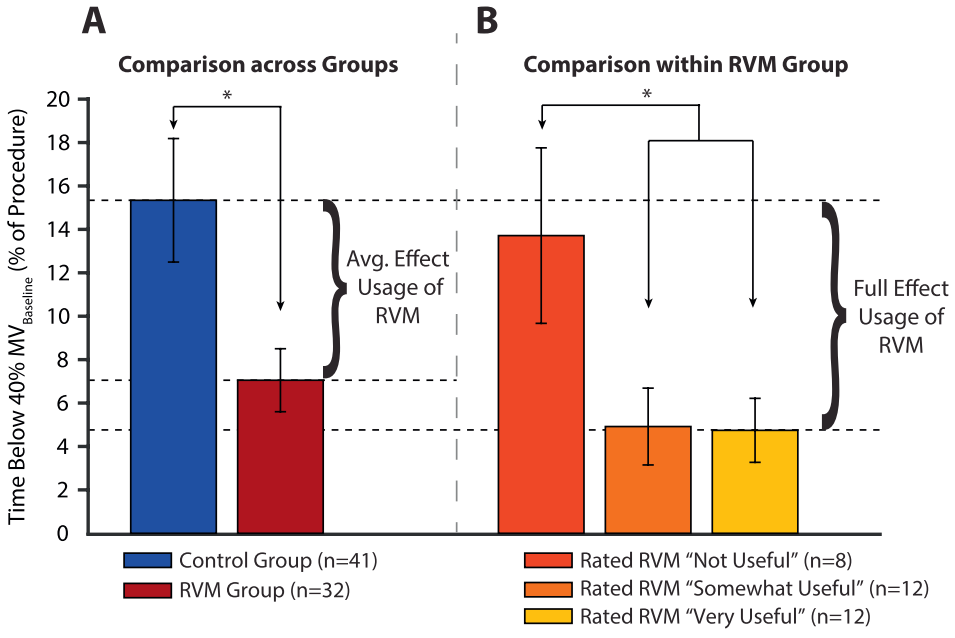

Fig. 3. A. Patients in the Control group (anaesthesiologist blinded to RVM) spent more than double the amount of time with Low MV compared to the entire RVM group (i.e., anaesthesiologist used RVM). B. Comparison within the RVM group showed that patients whose anaesthesiologist rated the RVM as "Not Useful" experienced a similar amount of time with Low MV compared to the Control group ($p = 0.81$). Patients whose anaesthesiologists found the RVM "Somewhat Useful" or "Very Useful" had a >50% reduction in time with Low MV compared to the "Not Useful" group ($p = 0.039$ and $p = 0.035$, respectively).

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the groups. Perhaps RVM monitoring allowed caregivers to intervene more quickly in settings of low MV than they otherwise would have. Interestingly, the number of airway maneuvers, such as jaw lifts, was similar between the two groups. Whatever the reason for improvement, these data support the usage of the RVM during complex upper endoscopy to direct care to improve patient ventilation and safety. It is logical that this clinical benefit would extend to other settings of procedural sedation.

While the ASA guidelines state that ventilation should be continuously monitoring during sedation [6], the majority of currently used clinical monitoring are either incapable of measuring ventilation or rely on secondary (lagging) indicators. Pulse oximetry provides a late indicator of respiratory depression [7,8], and capnography has proven to be unreliable in non-intubated patients [9–13]. Recent studies using the RVM have shown that capnography provides inadequate instrument sensitivity when detecting changes in ventilation in non-intubated patients [21,22], and decreases in MV proceed oxygen desaturations by an average of 13 min [23]. Furthermore, randomized control trials have shown the use of capnography does not improve patient safety compared to standard of care [24,25]. Analysis of the American Society of Anesthesiologists Closed Claims database showed that oversedation leading to respiratory depression was the most prevalent adverse event during Monitored Anesthesia Care cases [26]. Oversedation in these cases led to death or permanent brain damage in 84% of the claims and nearly half (44%) of the claims were deemed preventable with better monitoring. Further analysis of the same database revealed that procedures occurring outside the operating room had a higher incidence of respiratory depression and higher severity of injury than procedures performed in the operating room [27].

The finding that the results in the group of anaesthesiologists that did not see utility in the monitor were not different from the control group is interesting. Perhaps they did not see utility as they were not paying attention to the information: the data would support that interpretation. Presumably, those who found utility utilized the data to care for the patient in a way that was different from their normal care. The data support that interpretation as well. This speaks to the bigger issue that in order for new technology to improve patient care, the information provided needs to be incorporated into decision making [28].

This study had several limitations. First, the protocol for providing sedation, anesthesia, and analgesia was not identical across all patients as clinicians had to adjust care according to the patients' needs. However, on average across the two groups, the Control and RVM patients received similar amounts of propofol, midazolam, fentanyl, and ketamine. Since individual patients respond differently to similar levels of opioids and sedatives, a future study should use bispectral monitoring to compare sedation levels between groups. Furthermore, since the anesthesia-providers were aware they were participating in a research study, it is possible they adjusted the anesthesia dosing and number of airway maneuvers from what they otherwise would have during standard care due to the Hawthorne Effect. However, this effect should be present in both the RVM and Control groups and is therefore unlikely to have had a major impact on the results of the study. Next, whereas the RVM and Control groups had similar anthropometrics, the RVM group's patients were a bit older than the Control group (60.5 vs. 52.9 years). Since elderly patients are generally at a higher risk for respiratory depression [29], it is unlikely that the age difference contributed significantly to the results since we found less respiratory depression in the RVM group. Finally, the outcomes of this study were based on real-time RVM measurements only and not on long-term factors, like hospital re-admission, prolonged hospital stay, morbidity, or mortality. Note that there was no significant morbidity in the patients enrolled in this study.

This randomized control trial demonstrates the utility of the RVM's quantitative measurements of ventilation to reduce respiratory depression during procedural sedation for complex upper endoscopy. This is a pragmatic, 'real-world' demonstration that this new technology improves patient care.

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