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Microstream Capnography Improves Patient Monitoring During Moderate Sedation: A Randomized, Controlled Trial

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ABSTRACT

BACKGROUND. Investigative efforts to improve monitoring during sedation for patients of all ages are part of a national agenda for patient safety. According to the Institute of Medicine, recent technological advances in patient monitoring have contributed to substantially decreased mortality for people receiving general anesthesia in operating room settings. Patient safety has not been similarly targeted for the several million children annually in the United States who receive moderate sedation without endotracheal intubation. Critical event analyses have documented that hypoxemia secondary to depressed respiratory activity is a principal risk factor for near misses and death in this population. Current guidelines for monitoring patient safety during moderate sedation in children call for continuous pulse oximetry and visual assessment, which may not detect alveolar hypoventilation until arterial oxygen desaturation has occurred. Microstream capnography may provide an “early warning system” by generating real-time waveforms of respiratory activity in nonintubated patients.

OBJECTIVE. The aim of this study was to determine whether intervention based on capnography indications of alveolar hypoventilation reduces the incidence of arterial oxygen desaturation in nonintubated children receiving moderate sedation for nonsurgical procedures.

PARTICIPANTS AND METHODS. We included 163 children undergoing 174 elective gastrointestinal procedures with moderate sedation in a pediatric endoscopy unit in a randomized, controlled trial. All of the patients received routine care, including 2-L supplemental oxygen via nasal cannula. Investigators, patients, and endoscopy staff were blinded to additional capnography monitoring. In the intervention arm, trained independent observers signaled to clinical staff if capnograms indicated alveolar hypoventilation for >15 seconds. In the control arm, observers signaled if capnograms indicated alveolar hypoventilation for >60 seconds. Endoscopy nurses responded to signals in both arms by encouraging patients to breathe

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Key Words

monitoring, sedation, patient safety

Abbreviations

ETCO₂—end-tidal carbon dioxide

RN—registered nurse

EGD—esophagogastroduodenoscopy

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deeply, even if routine patient monitoring did not indicate a change in respiratory status.

OUTCOME MEASURES. Our primary outcome measure was patient arterial oxygen desaturation defined as a pulse oximetry reading of <95% for >5 seconds. Secondary outcome measures included documented assessments of abnormal ventilation, termination of the procedure secondary to concerns for patient safety, as well as other more rare adverse events including need for bag-mask ventilation, sedation reversal, or seizures.

RESULTS. Children randomly assigned to the intervention arm were significantly less likely to experience arterial oxygen desaturation than children in the control arm. Two study patients had documented adverse events, with no procedures terminated for patient safety concerns. Intervention and control patients did not differ in baseline characteristics. Endoscopy staff documented poor ventilation in 3% of all procedures and no apnea. Capnography indicated alveolar hypoventilation during 56% of procedures and apnea during 24%. We found no change in magnitude or statistical significance of the intervention effect when we adjusted the analysis for age, sedative dose, or other covariates.

CONCLUSIONS. The results of this controlled effectiveness trial support routine use of microstream capnography to detect alveolar hypoventilation and reduce hypoxemia during procedural sedation in children. In addition, capnography allowed early detection of arterial oxygen desaturation because of alveolar hypoventilation in the presence of supplemental oxygen. The current standard of care for monitoring all patients receiving sedation relies overtly on pulse oximetry, which does not measure ventilation. Most medical societies and regulatory organizations consider moderate sedation to be safe but also acknowledge serious associated risks, including suboptimal ventilation, airway obstruction, apnea, hypoxemia, hypoxia, and cardiopulmonary arrest. The results of this controlled trial suggest that microstream capnography improves the current standard of care for monitoring sedated children by allowing early detection of respiratory compromise, prompting intervention to minimize hypoxemia. Integrating capnography into patient monitoring protocols may ultimately improve the safety of nonintubated patients receiving moderate sedation.

THERE IS NO acceptable adverse-event rate for elective patient sedation during nonsurgical procedures.¹ According to the Institute of Medicine, technological advances in patient monitoring from 1960 to 1990 and carefully constructed guidelines have contributed to substantially decreased mortality from 1 per 5500 to 1 per 20 000 people receiving general anesthesia in operating room settings.²⁻⁴ Patient safety has not been similarly

targeted for the several million children annually in the United States who receive moderate sedation without endotracheal intubation.^{5,6} Critical event analyses have documented that hypoxemia secondary to depressed respiratory activity is a principal risk factor for near misses and death in this population.^{7,8} Investigative efforts to improve monitoring during sedation for patients of all ages are part of a national agenda for patient safety.^{2,5,9}

Continuous pulse oximetry in conjunction with visual assessment is the current standard of care for patient monitoring during pediatric moderate sedation.¹⁰⁻¹² The American Society of Anesthesiologists and the Joint Commission on Accreditation of Healthcare Organizations have defined moderate sedation as a drug-induced depression of consciousness along the continuum of sedation that maximizes comfort and cooperation without compromising airway integrity.^{13,14} More than 20 000 US children per year undergo gastrointestinal procedures,¹⁵ many with moderate or even deep procedural sedation.^{16,17} Recent prospective observational studies have suggested that real-time graphic assessment of ventilation using capnography in nonintubated patients undergoing sedated gastrointestinal procedures may complement current practice by providing an "early warning system" for impending respiratory compromise and resultant hypoxemia.^{18,19}

We examined the effectiveness of the recently advanced technology of microstream capnography at improving the safety of nonintubated children undergoing sedated procedures. Specifically, we investigated whether electronically monitoring respiratory activity reduces the incidence of arterial oxygen desaturation in pediatric patients undergoing moderate sedation for gastrointestinal endoscopy. We used a primary outcome of minor oxygen desaturation not as a surrogate for adverse events, but rather with the strong recognition that staff in our endoscopy unit are vigilant for early airway compromise.

METHODS

Study Design and Definitions

This prospective, double-blind, randomized trial contained 2 study arms. In both arms, standard of care ventilatory monitoring was performed by endoscopy staff, while independent observers silently recorded information obtained by microstream capnography (Philips M4 with Microstream CO₂, Philips Medical Systems, Andover, MA; Oridion Medical Inc, Needham, MA). In addition to absolute end-tidal carbon dioxide (ETCO₂) values, independent observers tracked continuous waveforms (capnograms) of expired carbon dioxide throughout the ventilatory cycle on the study capnometer.

In the intervention arm, independent observers signaled to endoscopy staff by a raised hand if capnograms

indicated alveolar hypoventilation, including apnea, for >15 seconds, as measured by a stopwatch (Fig 1). In the control arm, independent observers signaled if capnograms indicated alveolar hypoventilation for >60 seconds. Alveolar hypoventilation and apnea were defined as the persistent cessation of ventilatory waveforms.¹⁹⁻²¹ Signal criteria were based on ethical considerations, as well as published observational data, suggesting that short spans of capnograms consistent with alveolar hypoventilation are frequent in sedated patients,¹⁸ and patients who experience >45 seconds of alveolar hypoventilation are at risk for arterial oxygen desaturation.¹⁹ On signals from independent observers, endoscopy nurses (registered nurses [RNs]) repositioned patients' heads and encouraged them to breathe deeply with verbal instructions.

Our primary outcome variable was patient oxygen desaturation defined as a pulse oximetry reading of <95% for >5 seconds, (Nellcor Symphony N-3000 Pulse Oximeter with size-appropriate [adult, pediatric, or infant] OxiMax latex-free adhesive oxygen sensor, Nellcor Puritan Bennett Inc, Pleasanton, CA) with time also measured by stopwatch. This level of mild hypoxemia has been reported to precede adverse events.^{22,23} Secondary outcome measures included RN-documented assessments of abnormal ventilation, termination of the procedure secondary to concerns for patient safety (near misses), as well as other more rare adverse events, including the need for bag-mask ventilation, sedation reversal (ie, naloxone), or seizures. We hypothesized that acting on early capnographic indications of ventilatory compromise would decrease the incidence of oxygen desaturation, near misses, and other adverse events in children undergoing moderate sedation for gastrointestinal procedures.

The study was approved by the Children's Hospital Boston Committee on Clinical Investigation (institutional review board) and the Children's Hospital Boston General Clinical Research Center. Independent observers for the study (a General Clinical Research Center research nurse and a research assistant) were trained in capnography by a senior staff anesthesiologist. They then performed simultaneous monitoring of 5 "dry-run" patients who were not randomly assigned for analysis and biweekly silently watched each other record study data to ensure interobserver agreement of capnogram interpretation. Data coordination and randomization schemes were provided by the Clinical Research Program at Children's Hospital Boston.

Patients

Participants were recruited from all outpatients (December 2003 to November 2004) referred for elective procedures with moderate sedation in the endoscopy unit at a single, free-standing children's hospital. Primary gastroenterologists confirmed patient eligibility according to age (6 months to 19 years) and American Society of Anesthesiologists class (1: healthy; 2: single, controlled disease state).¹⁰ Exclusion criteria were American Society of Anesthesiologists classes 3 to 5, general anesthesia, emergency procedures, known seizure disorders, and use of mood-altering or chronic pain medications. Demographic information was collected for eligible participants. Written, informed consent was obtained on the day of procedure.

Randomization

Independent observers randomly assigned patients to study arms by opening pregenerated, sequentially numbered, opaque sealed envelopes. The randomization

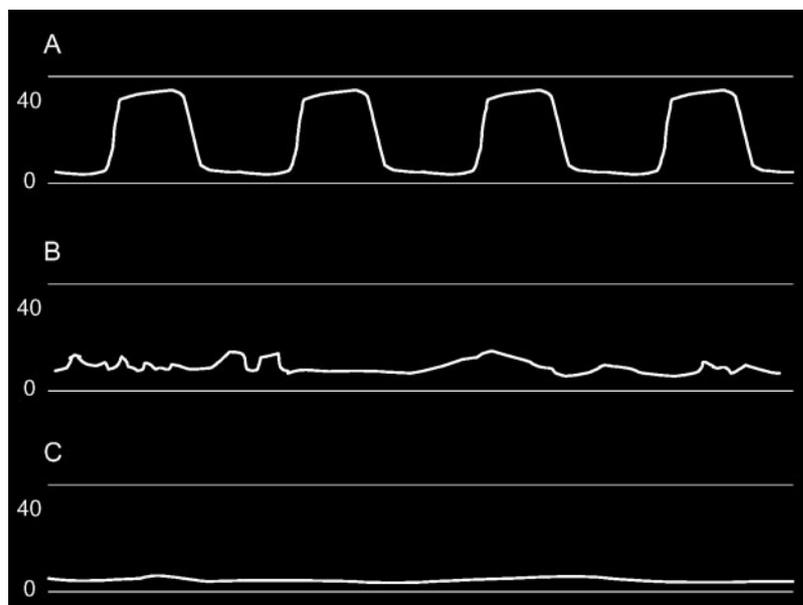


FIGURE 1
Example of normal capnogram (A), alveolar hypoventilation (B), and apnea (C).

scheme was permuted blocks of 2, 4, 6, and 8, stratified by procedure type (esophagogastroduodenoscopy [EGD] or colonoscopy). Participants undergoing combined EGD/colonoscopy were randomly assigned according to the first procedure planned. Investigators, patients, endoscopy unit staff (RNs and technicians), and endoscopists were blinded to study arm assignments.

Clinical Procedure

Sedation for endoscopy followed approved standardized protocols at our institution. Per endoscopist preference, some patients received oral midazolam (0.5 mg/kg; maximum dose: 20 mg) in preparation for peripheral intravenous catheter placement. All of the patients were continuously monitored for heart rate, respiratory rate, electrocardiogram, blood pressure, and pulse oximetry. Vital signs, visual assessment of patient chest wall excursion, and depth of sedation using the Ramsay scale (eg, 1 = patient awake, anxious, agitated or restless; 6 = anesthesia)²⁴ were documented every 5 minutes by dedicated RNs. An a priori sedation plan for all of the patients targeted moderate sedation, defined at our institution as the continuum of sedation at a Ramsay score of ≤ 4 (eg, patient asleep, purposeful response to a light stroke to the cheek).

A size-appropriate (infant, pediatric, or adult) nasal cannula with proboscis extending over the mouth provided 2 L of free-flowing oxygen and was equipped with an aspiration port for continuous sampling of CO₂ content of both inspired and expired patient gas samples (50 mL/minute) during either nasal or mouth breathing (Smart MAC-Line O₂ ET/CO₂ sampling lines, Oridion Medical Inc). Inspired samples were expected to contain essentially no CO₂ in the presence of supplemental oxygen; expired samples were expected to represent alveolar gas, with a small amount of gas containing no CO₂ from patient physiologic dead space. In the presence of alveolar hypoventilation, microstream samples contained increasing proportions of entrained ambient air with little to no CO₂.

In both study arms, gastrointestinal procedures proceeded routinely and patient care followed standard practice. Intravenous sedation with fentanyl (maximum dose: 5 μ g/kg) and midazolam (maximum dose: 0.3 mg/kg) was administered stepwise via slow intravenous push. Adequacy of sedation was determined by endoscopists. RNs monitored for deep sedation, defined as a Ramsay Score of ≥ 5 (eg, 5 = no response to a light stroke to the cheek but response to painful stimulus; 6 = anesthesia, no response to nail bed pressure).

On any evidence of inadequate ventilation detected by standard means, RNs intervened by repositioning patients, instructing patients to take a deep breath, providing supplemental blow-by oxygen (1–3 L via funnel), and alerting physicians to pause during the procedure or to withdraw the scope. RNs recorded any adverse events,

such as clinical signs of hypoventilation (respiratory rate < 10 breaths per minute), bradycardia (heart rate < 55 beats per minute), hypotension (systolic blood pressure < 80 in children > 1 year of age), vomiting, aspiration, or seizures, on a standardized sedation-monitoring record.

Capnography

In both study arms, the capnometer was muted and was visible only to independent observers. Capnometer waveforms were continuously generated throughout the respiratory cycle by measuring infrared absorption of aspirated gas samples at patient nares. CO₂ has peak absorption at 4200 nm with absorption at this wavelength proportional to Pco₂. Peaks in the capnogram correspond to expiration, whereas troughs correspond to inspiration. Distinct respiratory patterns are associated with specific waveforms.²⁵ Capnograms depicting alveolar hypoventilation were presumed representative of central depression of respiration, airway obstruction, or both.

Independent observers were trained to detect artifact in all electronic monitoring. Pulse oximetry readings were considered reliable if there was a steady pulse beat that correlated with plethysmography. Capnograms were considered reliable if nasal cannulae were in the nares, and the patient was not moving, verbalizing, or otherwise artifactually causing loss of waveform. Any concerns from clinical staff or independent observers that vital signs were not being adequately detected were addressed by the RNs repositioning the equipment, including nasal cannulae.

Independent observers recorded capnometer readings at least every 5 minutes from the time of intravenous sedation administration to the time of scope withdrawal. Incidence and time of capnograms indicating alveolar hypoventilation lasting > 15 seconds were noted. As a subset of alveolar hypoventilation, a flat line (absence of any CO₂ detection) lasting > 15 seconds on the capnometer was recorded as an episode of apnea.

Data Collection, Monitoring, and Safety

Data were recorded on paper forms and entered into a database via customized entry screens (SPSS Inc, Chicago, IL). All of the data were entered twice for verification and quality-control purposes. Adverse events were monitored by the principal investigator, graded by an independent consultant, and reported to the institutional review board within 72 hours.

Statistical Analysis

We conducted an intention-to-treat analysis. The primary null hypothesis, that equal proportions of intervention and control subjects would experience arterial oxygen desaturation, was addressed by a 2-sided Fisher's exact test. Other comparisons between arms were made by Fisher's exact test for dichotomous end points and the Wilcoxon (Mann-

Whitney) 2-sample test for continuous measures (many of which showed severely skewed distributions). To confirm the primary result adjusting for incidental variables (which were, in theory, balanced by randomization and, in fact, closely balanced as shown in Table 1) we performed multiple logistic regression analysis with arterial desaturation as the binary end point, study arm as the independent variable, and various patient characteristics and clinical outcomes as covariates. To test for effect modification we added arm \times covariate interaction to the regression model. The criterion for statistical significance in all of the tests was $P < .05$. SAS software (SAS Institute Inc, Cary, NC) was used for all of the computations.

Our analysis plan called for 1 interim analysis after 30 patients were randomly assigned. Sample size was chosen

on the basis of 9 cases of arterial desaturation observed at that point, or 30% in both arms combined, with 99% confidence interval 11% to 55%. No other interim analyses were planned or performed. Assuming an overall rate of 12% (just within the lower confidence bound), a sample of 174 provided 90% power to detect a fivefold reduction in intervention compared with control (4% vs 20%). The 5% type I error rate for the trial was not affected by use of the initial 30 patients, because the 2 trial arms were not separated, and blinding was maintained.²⁶

RESULTS

Participants

We randomly assigned 163 participants to an intervention or control arm before undergoing a total of 174

TABLE 1 Baseline Characteristics of Study Participants

Clinical Characteristic	Intervention (n = 83)	Control (n = 80)	P
Gender			
Male	46 (55)	43 (54)	.88 ^a
Female	37 (45)	37 (46)	
Race			
White	77 (93)	70 (88)	.30 ^a
Nonwhite	6 (7)	10 (13)	
Procedure			
Endoscopy	72 (87)	70 (88)	.98 ^a
Colonoscopy	11 (13)	10 (13)	
American Society of Anesthesiology class			
I	66 (80)	67 (84)	.55 ^a
II	17 (20)	13 (16)	
Maximum sedation level (Ramsey)			
2	16 (19)	10 (12)	.46 ^a
3	31 (37)	35 (44)	
4	36 (43)	35 (44)	
Artificial loss of capno waveform	83 (100)	80 (100)	—
Artificial loss because of patient talking	50 (60)	46 (58)	.75 ^a
Hypoventilation documented			
By RN	4 (5)	1 (1)	.37 ^a
By independent observer (>15 s on capnography)	43 (52)	51 (64)	.15 ^a
Apnea documented			
By RN	0 (0)	0 (0)	—
By independent observer (>15 s on capnography)	17 (20)	23 (29)	.28
Age, y	14.8 (0.7–18.9)	14.1 (0.5–18.7)	.14 ^b
Procedure duration, min			
Endoscopy	10 (0–24)	10 (4–25)	.65 ^b
Colonoscopy	39 (34–67)	40 (15–69)	.67 ^b
Sedation dose, mg/kg			
Oral midazolam	0 (0–0.5)	0 (0–0.5)	.53 ^b
Intravenous midazolam	0.14 (0.02–0.27)	0.13 (0.02–0.32)	.55 ^b
Intravenous fentanyl	2.0 (0.6–4.3)	2.2 (0.8–4.2)	.06 ^b
O ₂ , %			
Base	99 (95–100)	99 (97–100)	.44 ^b
Maximum	100 (97–100)	100 (97–100)	.85 ^b
ETCO ₂ , mm Hg			
Base	39 (26–50)	39 (17–50)	.63 ^b
Maximum	48 (30–67)	51 (27–62)	.20 ^b
Minimum	20 (6–45)	19 (6–50)	.77 ^b

Data are n (%) or median (range).

^a Testing equal proportions in control and intervention arm, from 2-sided Fisher's exact test.

^b Testing equal distributions in control and intervention arm, from Wilcoxon 2-sample test.

procedures (Fig 2). To eliminate issues of correlated response within a given patient's data, we analyzed only the first procedure for each patient, reducing the sample size to 163 but only negligibly reducing power. Indications for gastrointestinal procedures included gastroesophageal reflux (56 patients), abdominal pain (37), vomiting (14), rectal bleeding (13), and diarrhea (12). Procedures performed included EGDs (131 patients), colonoscopy (21), and EGD with colonoscopy (11). Before intravenous insertion, 14 patients received oral midazolam. Baseline characteristics of an additional 16 eligible patients who declined to participate did not differ significantly from participants. Intervention and control patients did not differ significantly in baseline characteristics or procedural times (Table 1).

Primary Outcome Measure

Patients in the intervention arm were significantly less likely to have an intraprocedural episode of arterial oxygen desaturation to <95% than those in the control arm (11% vs 24%; $P < .03$; Table 2). Several clinical characteristics and covariates were significantly associated with desaturation (eg, detection of apnea by capnography or detection of hypoventilation by the RN), but controlling for these variables in multiple regression analysis did not reduce the magnitude or statistical significance of the intervention effect. Adjustment for covariates in fact strengthened the point estimate of the intervention effect, although it widened the confidence interval (Table 2). No interaction between intervention arm and covariates was detected.

Two patients in the control arm had a pulse oximetry reading of <95% for >5 seconds without defined alveolar hypoventilation on capnography. All of the other patients experienced arterial desaturation for a mean of

3.4 minutes (median: 1 minute; range: 0–13 minutes) after capnograms first depicted alveolar hypoventilation with no differences in time to desaturation between control and intervention arms ($P > .40$).

Secondary Outcome Measures

No procedures were terminated for patient safety concerns. There were no rare adverse events during the study period, including no need for bag-mask ventilation, sedation reversal, cardiovascular instability, or seizures. Two study patients experienced adverse events: 1 vomited on awakening from moderate sedation in the postanesthesia care unit, whereas the other failed to sedate with standard doses of sedation. Neither adverse event was determined to be related to participation in the study or to the use of capnography.

Dedicated Nurse Assessments of Ventilation

Endoscopy RNs documented poor ventilation during 5 (3%) procedures and no episodes of apnea. During all of the procedures, RNs frequently checked and repositioned patients to optimize ventilation, independent of any signals from study observers. Supplemental blow-by oxygen via funnel was provided intermittently throughout many procedures. One patient experienced transient arterial oxygen desaturation to 79% for <1 minute and received active airway intervention (chin lift). No study patient received jaw lift, bag-mask ventilation, or endotracheal intubation.

Pulse Oximetry

Twenty-nine (18%) patients had a pulse oximetry reading of <95% for >5 seconds at least once during sedation with 2-L supplemental O₂ via nasal cannula. Baseline arterial oxygen saturations obtained from all of the

FIGURE 2
Trial flow diagram.

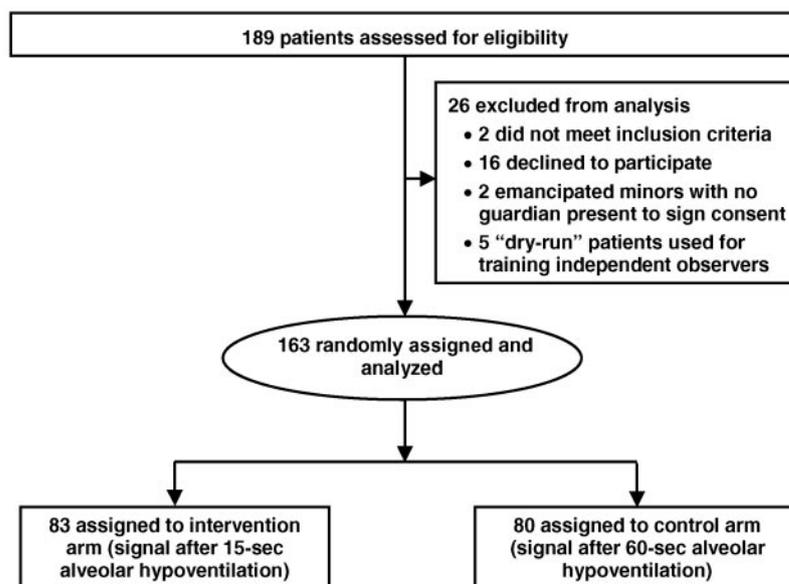


TABLE 2 Patients in the Intervention Arm Were Significantly Less Likely to Become Hypoxemic Than Those in the Control Arm

Variable	O ₂ Desaturation	P
Intervention (83) (>15 s alveolar hypoventilation), n (%)	9 (10.8)	.024 ^a
Control (80) (>60 s alveolar hypoventilation), n (%)	20 (25.0)	
Simple logistic regression, OR (95% CI)	0.36 ^b (0.15–0.87)	.022
“Best” model, OR (95% CI) ^c	0.29 ^b (0.10–0.84)	.020
Full model, OR (95% CI)	0.17 ^b (0.04–0.71)	.015

OR indicates odds ratio; CI, confidence interval.

^a Fisher’s exact test for equal likelihood of O₂ desaturation in intervention and control arms.

^b These are the odds of O₂ desaturation in the intervention group divided by odds in control group; a small value indicates protective effect of intervention. Odds ratio = 1 (null value) obtained from logistic regression with O₂ desaturation as dependent variable and trial arm as independent variable.

^c “Best” model from stepwise selection of covariates included detection of apnea or disordered breathing by capnography or hypoventilation by RN; the full model included all covariates listed in Table 1.

patients without supplemental O₂ ranged from 95% to 100%, with a mean and median of 99%. When 2-L supplemental O₂ via nasal cannula was applied before the procedure, only 6 (5%) study patients did not reach a maximum arterial saturation of 99% to 100%.

Capnography

More than 15 seconds of alveolar hypoventilation was noted on capnography in 58% (94) of patients and 56% (98) of procedures. More than 15 seconds of apnea on capnography was noted in 25% (40) of patients and 24% (42) of procedures. Transient loss of waveform because of talking, moving, crying, or other artifact happened during every procedure.

Baseline ETCO₂ readings obtained at the time of intravenous sedation administration ranged from 17 to 50 (median: 39) and included 3 patients with baseline ETCO₂ readings of <20 who were crying. The highest ETCO₂ reading obtained from each participant during procedure time ranged from 27 to 67 (median: 50) and included 2 children with ETCO₂ readings of <35. There were no differences between intervention and control arms in median maximum ($P = .20$) or minimum ($P = .77$) ETCO₂ readings.

Maximum ETCO₂ values were similar between patients who had a pulse oximetry reading of <95% for >5 seconds ($P = .20$) or patients who had capnograms consistent with alveolar hypoventilation for >15 seconds ($P = .64$). Minimum ETCO₂ values were significantly lower in those patients with arterial desaturation ($P = .05$) and those with capnograms consistent with alveolar hypoventilation ($P < .0001$). In these patients, alveolar hypoventilation resulted in the largest portion of the aspiration ETCO₂ sample being composed of room air and supplemental oxygen devoid of CO₂ rather than of CO₂-rich alveolar gas.

DISCUSSION

The results of this controlled effectiveness trial indicate that stimulation of moderately sedated patients in response to abnormal capnograms is associated with fewer

incidents of arterial oxygen desaturation as measured by continuous pulse oximetry. According to the American Society of Anesthesiologists and the American Academy of Pediatrics, the term “moderate sedation” should replace the more commonly used term “conscious sedation” and involves active continual patient assessment for deep sedation with possible ventilatory compromise.^{12,13} Our results support the routine use of microstream capnography to improve detection of alveolar hypoventilation and reduce arterial oxygen desaturation during moderate sedation for pediatric procedures.

In addition, capnography allowed early detection of arterial oxygen desaturation because of alveolar hypoventilation in the presence of supplemental oxygen. It has been suggested that providing supplemental oxygen during procedural sedation may mask early detection of inadequate ventilation by continuous pulse oximetry.¹⁰ At the same time, it has been shown that withholding supplemental oxygen significantly shortens the interval between respiratory compromise and arterial desaturation.¹¹ Integrating capnography into sedation protocols solves this dilemma by allowing for routine administration of supplemental oxygen without compromising patient monitoring.

Catastrophic adverse events during moderate sedation for nonemergent pediatric procedures are rare, but almost all are directly linked to failure to rescue from impending respiratory failure.⁷ Several studies of pediatric sedation have demonstrated a direct link between arterial oxygen desaturation as detected by pulse oximetry and poor outcomes.^{7,8,27} The current standard of care for monitoring all patients receiving sedation^{11,12} relies overtly on pulse oximetry, which does not measure ventilation.^{5,10} Early detection of alveolar hypoventilation in patients undergoing moderate sedation may be valuable in avoiding significant morbidity and mortality.⁵

Recent advances in lightweight compact microstream capnography technology allow the easy, accurate, real-time graphic display of ventilatory waveforms in nonintubated patients.^{28,29} Different from conventional mainstream capnometers, which use blackbody infrared

technology that is vulnerable to interference by other infrared absorbing molecules, such as water vapor, microstream capnography uses molecular correlation spectroscopy that is highly selective for carbon dioxide.²⁹ Compared with validated older technologies, including mainstream capnometers,²⁸ pretracheal stethoscopes,¹⁹ and direct arterial carbon dioxide partial pressure sampling,³⁰ microstream capnography shows less potential for inaccurate measurements and fewer technical disadvantages.³¹

Observational studies substantiate our finding that continuous monitoring by capnography is feasible in very young children.^{31–34} The results of our study may be generalizable to adult populations in a variety of settings.^{35,36} In moderately sedated adults undergoing endoscopic retrograde cholangiopancreatography with routine ventilatory monitoring, Vargo et al¹⁹ reported that 57% had ≥ 1 episode of apnea or disordered respiration detected by capnography and not detected by standard monitoring. The results of our study support capnograms, rather than absolute ETCO_2 values, as the most sensitive measure of ventilation in nonintubated patients.^{19,36}

Our study relied on detection of arterial oxygen desaturation by conventional pulse oximetry, and our results might have been different if newer oximetry technologies with improved clinical accuracy had been used.^{37,38} Another limitation to our study is that some occurrences of capnograms consistent with alveolar hypoventilation may have instead been artifact, and independent observers could have, in effect, signaled nuisance alarms to RNs. Generally speaking, we designed this study as an effectiveness trial that took place in the real world of our endoscopy unit. To this end, we used our own conventional pulse oximeters and definitions of capnograms that we felt could be easily and feasibly adopted clinically.

Of course, few adverse events occurred, and use of capnography cannot be directly linked to improved patient safety. We chose minor oxygen desaturation to $< 95\%$ as the primary outcome measure, in part because it represents a consensus threshold point in our endoscopy unit and others^{16,17} at which staff act to stimulate a sedated child out of concern that the child is not optimally ventilating. Our primary outcome measure is not intended to be a surrogate for significant adverse events but rather represents a point at which the operating environment in our endoscopy unit is altered by staff concern for patient safety.

As with aviation safety paradigms,³⁹ the target “crash rate” for moderate sedation in relatively healthy patients is 0. Pilots are trained to act early on indications that their plane is in distress. Clinicians will often intervene to stimulate patient respiration if a pulse oximeter detects minor arterial desaturation, a relatively late sign of suboptimal ventilation.²⁷ Acting even earlier by adopting

a “new cockpit dial,” such as capnography, may be warranted and valuable in avoiding significant morbidity and mortality.

Most medical societies and the Joint Commission on Accreditation of Healthcare Organizations consider moderate sedation to be safe but also acknowledge serious associated risks, including suboptimal ventilation, airway obstruction, apnea, hypoxemia, hypoxia, and cardiopulmonary arrest.^{9,11–13,40} The results of this controlled trial suggest that microstream capnography improves the current standard of care for monitoring sedated children by allowing early detection of respiratory compromise, prompting intervention to minimize hypoxemia. Used in conjunction with pulse oximetry and visual assessment, capnography may ultimately improve patient safety during moderate sedation for pediatric procedures.

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