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A Single-blind Study of Pulse Oximetry in Children

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Oxygen saturation determined by pulse oximetry was monitored in 152 pediatric surgical patients divided into two groups. In one group, the oximeter data and alarms were available (N = 76) to the anesthesia team, and, in the other group, these data were unavailable (N = 76). A trained observer recorded all intraoperative hypoxic episodes and informed the anesthesia team of all major events (*i.e.*, oxygen saturation ≤ 85% for ≥30 s) (Pa_{O_2} approximately 52 mmHg). Thirty-five major events occurred: 24 in the unavailable group, and 11 in the available group ($P = 0.021$). A greater number of major events occurred in children ≤ 2 yr of age ($P = 0.013$). Hypoxic events diagnosed by the oximeter, but not by the anesthesiologist, were more frequent in the unavailable group (13) than in the available group (5) ($P = 0.0495$). ASA Physical Status 3 and 4 patients were more likely to suffer a major event ($P = 0.009$ available, 0.006 unavailable). The pulse oximeter diagnosed hypoxemia before the signs and symptoms of hypoxemia were apparent (*i.e.*, prior to observed cyanosis or bradycardia). Major hypoxic events were unrelated to duration of anesthesia. Major events were evenly distributed among induction, maintenance, and awakening from anesthesia; a greater number of hypoxic events occurred during induction in the unavailable group ($P = 0.031$). No morbidity was documented in any patient who suffered an hypoxic event. More patients experienced borderline oxygenation in room air at the end of anesthesia (≤90% saturation) in the unavailable group (12 of 60) than in the available group (3 of 57) ($P = 0.009$). The authors conclude that pulse oximetry, in contrast to changes in vital signs, does provide an early warning of developing hypoxemia in anesthetized children. (Key words: Anesthesia: pediatric. Monitoring: oximetry. Oxygen: oxygen saturation.)

PULSE OXIMETRY represents the latest in a series of new monitoring devices[1] and provides an accurate assessment of oxygen saturation in a totally non-invasive manner, even in critically ill patients.[2-5] To examine the efficacy of this device in the early recognition of hypoxic events, we conducted a prospective, single-blind study in pediatric patients undergoing either elective or emergency operations.

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Materials and Methods

The protocol for this study was institutionally approved, and written consent was obtained for each patient. All pediatric surgical patients at the Massachusetts General Hospital were considered candidates for study. Children were monitored in our usual manner: precordial stethoscope, blood pressure, electrocardiogram, temperature, inspired oxygen, and expired carbon dioxide; the anesthetic prescription was chosen by the physicians caring for the patient. A pulse oximeter sensing device was placed on the patient's finger or toe prior to or shortly after induction of anesthesia (Nellcor, Inc., Hayward, CA); the pulse oximeter (N-100) was equipped with a strip-chart recorder (N-9000), and a continuous recording was made during the entire anesthetic procedure. Patients were assigned consecutive numbers as they entered the study. The information from the oximeter and its alarms was available to the anesthesia team throughout for even-numbered patients. The odd-numbered patients had the monitor turned away from the anesthesia team, and the alarms were disabled. The oxygen saturation alarm limit was set for 85%, which corresponds to a Pa_{O_2} of approximately 52 mmHg. A trained observer was continuously present, recording all intraoperative events and making notations on the strip-chart recordings immediately after each event occurred; events were timed with a stop-watch. The observer remained in a position well away from the anesthesiologist so as not to compromise the blindness of the study. The duration of events and the degree of desaturation were later confirmed by review of the recordings.

Those patients whose oximeter data were available to the anesthesia team comprised the "available" group; those patients whose oximeter data were blinded from the anesthesia team formed the "unavailable" group. Major events were those in which the oxygen saturation was ≤85% for 30 s or longer; minor events, ≤85% for <30 s; and interesting events, ≤90% but >85%. If the alarms were not available, and 30 s had passed with the

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TABLE 1. Characteristics of the Study Groups (Mean ± SD)

	Available	Unavilable	Range
Number	76	76	
Age (yr)	4.23 ± 4.17	4.47 ± 4.23	Newborn–15
Weight (kg)	20.1 ± 17.6	18.7 ± 13.5	1.67–110
Duration of anesthesia (min)	57.1 ± 58	62.8 ± 54.9	4–291
In-patient	17	20	
Out-patient	59	56	

saturation ≤85%, the observer informed the anesthesia team that desaturation had occurred.

Immediately after a major event occurred, whether the oximeter data were available or unavailable, the observer interviewed the individual providing anesthesia to determine whether the oximeter had made the diagnosis before the anesthesiologist had recognized a problem. In addition, any change in vital signs observed by the anesthesiologist was noted. Other recorded data included patient age and weight, ASA physical status, heart rate as determined by both the oximeter and electrocardiograph (a single observation for each patient shortly after induction), surgical procedure, in-patient or out-patient surgical facility, duration of surgery and anesthesia, oxygen saturation while receiving oxygen just prior to termination of anesthesia, oxygen saturation nadir after termination of anesthesia, and saturation after stabilization while breathing room air.

STATISTICAL METHODS

To compare the rates of major events in the unavailable and available groups, we regarded the number of major events in each group as a Poisson count. A binomial test for equality of the underlying rates of occurrence (per study) was applied. The same analysis was used to compare rates of minor, interesting, and major events diagnosed by the oximeter between the two groups, as well as to compare rates of major events within age categories, within weight categories, and during induction. The z test for binomial proportions was used to compare the proportion of studies that had a major event 1) between broad categories of anesthetic risk within the two groups, and 2) between the two groups within risk category 3 and 4. The z test was also used to compare studies in which the patient experienced moderate desaturation in room air. Comparisons of the two groups on background variables used the *t* test (age, weight, duration of anesthesia) and the z test (risk category, in-patient and out-patient). A P value < 0.05 was considered significant.

Results

One hundred and fifty-five patients were studied. Table 1 presents the characteristics of the two groups. The available and unavailable groups did not differ significantly in mean age, weight, ASA physical status, number of in-patients or out-patients, or duration of anesthesia. Thirty-eight major events occurred in 28 patients. Two patients, one of whom had a major event, were excluded from the data analysis because of unusually long surgical procedures (665 and 457 min). One other patient, who had two major events, was also excluded because of a departure from the protocol. Thus, three patients with three major events were deleted from the final data analysis. Sixty-four minor and 75 interesting events occurred in all 155 patients. The data for the 152 non-excluded patients are in table 2. For these 152 cases, 17.1% had at least one major event, 29.6% one minor event, and 28.3% one interesting event. A significantly greater number of major ($P = 0.021$), but not minor (P = NS) or interesting ($P = 0.051$), events occurred in studies where the oximeter information was unavailable. A greater number of major events occurred in children ≤ 2 yr of age ($P = 0.013$); there was a tendency for a greater number of major events to occur in children ≤ 10 kg ($P = 0.058$). Major events diagnosed by the oximeter, but not by the anesthesiologist, were more frequent in the unavailable group (13) than in the available group (5) ($P = 0.0495$). The major hypoxic events diagnosed by the oximeter prior to diagnosis by the anesthetizing team included: four cases of airway obstruction, three cases of laryngo-

TABLE 2. Distribution of Major Events by Age and Weight*

	Available		Unavailable		P
	Major Events	(N)	Major Events	(N)	Value
Age (yr)					
≤2	7	(33)	19	(32)	0.013
3–6	4	(23)	1	(23)	0.963
7–12	0	(16)	3	(16)	0.124
>12	0	(4)	1	(5)	0.545
Total	11	76	24	76	
Weight (kg)					
≤10	6	(23)	13	(21)	0.058
>10	5	(53)	11	(55)	0.120

* Some patients had more than one major event. This table excludes two patients with three major events; see Methods section.

TABLE 3. Major Events, ASA Physical Status 1 and 2 *Versus* 3 and 4*

Physical Status	1 and 2 *Versus* 3 and 4				
Available	6/58	0/10	0/3	3/5	$P = 0.009$
Unavailable†	8/55	4/12	3/5	2/4	$P = 0.006$

* Some patients had more than one major event. This table excludes two patients with three major events; see Methods section.
† Available *versus* unavailable, $P = 0.23$.

spasm, three cases of hypoventilation, and three atelectases in the unavailable group, and one each of airway obstruction, laryngospasm, hypoventilation, atelectasis, and endobronchial intubation in the available group. ASA Physical Status 3 and 4 patients were more likely to experience major hypoxic events than were risk category 1 and 2 patients in both available ($P < 0.009$) and unavailable ($P < 0.006$) groups (table 3); risk category 3 and 4 patients, however, did not differ in their incidence of major hypoxic events between available and unavailable groups ($P = 0.23$).

The total time during which oxygen saturation was ≤90% and ≤85% was greater in the unavailable group (89.0 and 41.6 min) than in the available group (50.9 and 26.7 min). The occurrence of major events was evenly divided between induction (defined as the time from first drug administration until either tracheal intubation or stable mask ventilation), maintenance, and awakening (defined as the time at which anesthetic agents were terminated and the patient breathed room air prior to arriving in the recovery room) (table 4). A greater number of major events occurred during induction in the unavailable group than in the available group ($P = 0.031$). There was no relationship of major events to duration of anesthesia; some patients experienced more than one hypoxic event during brief operative procedures, whereas others experienced no hypoxic events during long operative procedures. There was no relationship between visible cyanosis and desaturation documented by the oximeter. Of the 11 hypoxic episodes in the available group, four were described as cyanotic, four as not cyanotic, and, in three, the degree of cyanosis was not determined; of the 24 hypoxic episodes in the unavailable group, ten were described as cyanotic, 12 as not cyanotic, and, in two, the degree of cyanosis was not determined. All 14 patients described as cyanotic had a saturation ≤ 72% (Pa_{O_2} approximately 40 mmHg); nine patients with saturation < 72%, however, were not described as cyanotic.

TABLE 4. Distribution of Major Events during Anesthesia*

	Induction	Maintenance	Awakening
Available	3	3	5
Unavailable	11†	6	7

* Some patients had more than one major event. This table excludes two patients with three major events; see Methods section.
† $P = 0.0310$, available *versus* unavailable.

Vital signs were of little value in diagnosing desaturation: heart rate did not change in 33 episodes, increased in one, and decreased in one; in two episodes, a fall in blood pressure was noted, in one blood pressure increased; a change in the respiratory pattern was noted in two and decreased quality of the heart tones in one. Eighteen of 35 events were diagnosed by the oximeter rather than by the anesthesiologist; in only four of these was any change in vital signs noted. On one occasion, the oximeter showed a saturation of 78%. The anesthesiologist did not believe the oximeter and, therefore, obtained an arterial blood gas determination; the Pa_{O_2} was 48 mmHg. Twenty-three blood gases were obtained for reasons other than desaturation; all had Pa_{O_2} > 100 mmHg as the oximeter saturation read 99–100%. The heart rate (mean ± SEM) obtained with the pulse oximeter (114 ± 2.5) correlated well with that obtained with a standard electrocardiograph (113 ± 2.5; $r = 0.99$, $P < 0.0001$).

The incidence of major events was not related to the experience of the anesthesiologist or to duration of anesthesia; major unrecognized hypoxic events occurred with staff anesthesiologists, fellows, CRNAs, and first- and second-year residents administering anesthesia.

The number of episodes of moderate desaturation (≤90%) but not severe desaturation (≤85%), prior to transport of the patient to the recovery room, was significantly higher in the unavailable group (12 of 60 *versus* 3 of 57; $P = 0.009$). The mean oxygen saturation after the patient had breathed room air for several minutes, however, was not significantly different between available (96.2 ± 0.4%) and unavailable groups (94.7 ± 0.5%).

Transient desaturation commonly occurred during manual ventilation, while the anesthesiologist was performing routine procedures, such as injection of medications, nasogastric or tracheal suction, and changing intravenous fluids.

Discussion

Whenever new and relatively expensive technology is introduced, it is important to ascertain its efficacy. Our study sought to determine whether pulse oximetry would help to diagnose hypoxic events missed by the anesthesiologist when relying on the usual available signs, *i.e.*, cyanosis, bradycardia, change in the quality of heart tones, or respiratory pattern. We found pulse ox-

imetry to be a highly useful adjunct because it permitted earlier detection of hypoxemia than the usual means. Major unrecognized hypoxic events occurred at all levels of anesthesia expertise (staff, fellow, resident, nurse anesthetist); *i.e.*, the experience and training of the anesthesiologist did not alter the ability to detect major episodes of desaturation by the usual criteria. This conclusion is supported by the fact that cyanosis was more commonly diagnosed when the oxygen saturation was 72% or less (Pa_{O_2} = 40 mmHg), and by the fact that changes in heart rate, respiratory pattern, and quality of heart tones were noted in only six of 35 major hypoxic events and in only four of 18 unrecognized episodes of desaturation. Arterial desaturation precedes the clinical signs and symptoms of hypoxemia. These observations are consistent with the more rigorous study by Comroe and Botelho, who found wide variations in the ability of even experienced observers to detect cyanosis at saturations of 70–80%. Their conclusion and ours is that "Visual impressions of cyanosis are unreliable."[5]

Heart rate changes did not provide any information that would improve the early detection of major arterial desaturation, because a change in heart rate is a late sign of hypoxemia (two out of 35 events); similarly, retrospective studies of adult patients found that electrocardiographic monitoring was of minimal value in preventing cardiac arrest due to hypoxemia.[6,7]

The overall incidence of major hypoxic events was unexpected, but even more impressive is the fact that those patients whose anesthesiologists did not have the oximeter data immediately available to them (the routine standard of practice prior to pulse oximetry) experienced a greater number of major hypoxic events and an increased total time of hypoxemia; this suggests that oximetry helped to guide anesthetic management. Because interviews were conducted in the operating room immediately after the major events occurred, the resident, staff, or nurse anesthetist had to admit whether he/she was aware of a hypoxic event; thus, if there was any bias in this study, it was against the oximeter.

The occurrence of major events was evenly distributed in both groups among induction, maintenance, and awakening; this reaffirms that the conduct of anesthesia requires constant vigilance throughout the case, regardless of the experience of the anesthesiologist.[5,7–10] The reason for the higher incidence of major events during induction of anesthesia in the unavailable group is unclear, but, during this time, physiologic responses to anesthetic medications occur most rapidly.

There was no relationship of major hypoxic events to duration of anesthesia; multiple hypoxic events occurred during short simple cases, and no or one event during long complex procedures. For example, one computerized axial tomography case had five events in 45 min, and a single hypoxic event occurred during a 13-h liver transplant.

Major hypoxic events were more likely to occur in children 2 yr of age or less and in ASA physical status category 3 and 4 patients. This may happen because infants have a markedly higher oxygen consumption than older children and, therefore, desaturate more rapidly;[11] it may also reflect the technical difficulty of caring for young patients. Hypoxemia is one of the major contributing factors to the reported threefold higher incidence of intraoperative cardiac arrest in children compared to adults;[6] the increased incidence of major hypoxic events in higher-risk children agrees with similar studies of adult patients.[6,7,12,13]

The anesthesiologist's use of clinical signs and symptoms of hypoxemia did not adequately diagnose those patients with borderline oxygenation. This is confirmed by the high incidence of steady-state borderline oxygenation when patients breathed room air at the end of anesthesia; 20% of the unavailable group, but only 5% of the available group, demonstrated steady-state saturations of ≤90%, equivalent to a Pa_{O_2} of approximately 60 mmHg. This observation is identical to that of Tyler *et al.*, who found a 21% incidence of moderate hypoxemia in postoperative adult patients;[14] both studies demonstrate that post-anesthetic hypoxemia is common despite adequate washout of nitrous oxide. The fact that the children who had the benefit of oxygen saturation data available to their anesthesiologist returned to the recovery room with fewer episodes of borderline oxygenation also indicates that the pulse oximeter helped the anesthesiologist to decide when the patient could safely be transported.

Many routine aspects of anesthetic care (such as administering intravenous medications and blood, suctioning the mouth or trachea, or passing a nasogastric tube) resulted in transient episodes of desaturation (interesting and minor events) in patients being manually ventilated. These events were not of any clinical significance.

We observed many artifacts; inappropriate sensor size resulted in the inability to obtain a recording, but placing an adult sensor around the entire hand or foot of an infant often produced excellent results. Placing the sensor on the same limb as the blood pressure cuff resulted in the alarm sounding every time the blood pressure was taken. Electrocautery frequently disrupted the signal, as did movement, pressing on the sensor, direct high-intensity light, and a variety of routine operating room procedures, such as inserting an intravenous catheter, positioning the patient, and applying dressings. We did not have any difficulty with vasoconstriction secondary to hypoperfusion or hypothermia in

children; however, we have had this problem with adult patients.

Studies of anesthetic-related morbidity and mortality have found that approximately 80% are preventable; the majority of life-threatening events from hypoxemia are due to inappropriate management (endobronchial or esophageal intubation, anesthetic overdose), failure in proper monitoring (not listening to breath sounds or heart tones), accidental extubations, and equipment disconnections.[8-10,15-20] True equipment failure is rare.[20] Human factors, such as fatigue, are also important in the etiology of anesthetic mishaps.[8,15,17-19] New technology can be enormously expensive to purchase and equally costly to use and maintain. A recent study of information feedback and pulse oximetry on the incidence of anesthesia-related complications found that only the incidence of hypotension and hypovolemia changed after the introduction of pulse oximetry. That study, however, was flawed by the lack of rigorous controls and the method by which data were collected.[13] However, in our judgment, oximeters will save many lives by facilitating the early recognition of hypoxic events before they result in morbidity or mortality. We were able to re-use "disposable" sensors many times, reducing the cost to approximately $1.00 per patient. Perhaps if insurance carriers encouraged the adoption of improved technology through such incentives as reduced malpractice insurance costs, more individuals would use these monitoring devices.[21] The use of this monitor in other situations that involve heavy sedation or ventilatory support (such as the intensive care unit, emergency room, and dental office) may well reduce morbidity in these locations by providing an early warning of hypoxemia as it develops.

Pulse oximetry is a sensitive, reliable, non-invasive measure of oxygen saturation, capable of diagnosing and providing an early warning of desaturation prior to the development of the signs and symptoms of hypoxemia, regardless of the experience of the observer.

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