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Randomized Evaluation of Pulse Oximetry in 20,802 Patients: II.

Perioperative Events and Postoperative Complications

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Background: **The authors describe the effect of pulse oximetry monitoring on the frequency of unanticipated perioperative events, changes in patient care, and the rate of postoperative complications in a prospective randomized study.**

Methods: **The study included 20,802 surgical patients in Denmark randomly assigned to be monitored or not with pulse oximetry in the operating room (OR) and postanesthesia care unit (PACU).**

Results: **During anesthesia and in the PACU, significantly more patients in the oximetry group had at least one respiratory event than did the control patients. This was the result of a 19-fold increase in the incidence of diagnosed hypoxemia in the oximetry group than in the control group in both the OR and PACU ($P < 0.00001$). In the OR, cardiovascular events were observed in a similar number of patients in both groups, except myocardial ischemia (as defined by angina or ST-segment depression), which was detected in 12 patients in the oximetry group and in 26 patients in the control group ($P < 0.03$). Several changes in PACU care were observed in association with the use of pulse oximetry. These included higher flow rate of supplemental oxygen ($P < 0.00001$), increased use of supplemental oxygen at discharge ($P < 0.00001$), and increased use of naloxone ($P < 0.02$). The rate of changes in patient care as a consequence of the oximetry monitoring increased as the American Society of Anesthesiologists physical status worsened ($P < 0.00001$). One or more postoperative complications occurred in 10% of the patients in the oximetry group and in 9.4% in the control group (difference not significant). The two groups did not differ significantly in cardiovascular, respiratory, neurologic, or infectious complications. The duration of hospital stay was a median of 5 days in both groups (difference not significant). An equal number of in-hospital deaths were registered in the two groups. Questionnaires, completed by the anesthesiologists at the five partic-**

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ipating departments, revealed that 18% of the anesthesiologists had experienced a situation in which a pulse oximeter helped to avoid a serious event or complication and that 80% of the anesthesiologists felt more secure when they used a pulse oximeter.

Conclusions: **This study demonstrated that pulse oximetry can improve the anesthesiologist's ability to detect hypoxemia and related events in the OR and PACU and that the use of the oximeter was associated with a significant decrease in the rate of myocardial ischemia. Although monitoring with pulse oximetry prompted a number of changes in patient care, a reduction in the overall rate of postoperative complications was not observed. (Key words: Complications, hypoxemia: intraoperative; postoperative. Monitoring outcome: pulse oximetry. Study design: prospective, randomized.)**

PRECISION, efficacy, and application of pulse oximeters have been investigated repeatedly during the past 7–8 years.[1–6] Only three previous studies have examined whether monitoring with a pulse oximeter reduces the incidence and degree of hypoxemia.[7–9] Only one study has evaluated, in a prospective but not randomized design, the impact of pulse oximetry on the rate of events during anesthesia and recovery.[10] Although significantly fewer events were recorded after the introduction of pulse oximetry, the investigators did not draw definitive conclusions because of confounding factors. Moreover, all these previous studies did not answer the question: Does perioperative monitoring with a pulse oximeter reduce postoperative morbidity? This critical inquiry requires controlled prospective clinical studies of pulse oximetry and other monitoring modalities.[11]

In this article, we report the results of a prospective randomized study of pulse oximetry monitoring in the operating room (OR) and postanesthesia care unit (PACU). The principle aims were to evaluate the effect of pulse oximetry monitoring on the detection of unanticipated events, changes in patient care, and the rate of postoperative complications and interventions. Our working hypotheses were that pulse oximeter monitoring would increase the identification of hypoxemic episodes, decrease some undesired events, and especially decrease postoperative cardiopulmonary complications. We also evaluated, by questionnaire, the opinion of the participating anesthesiologists and their self-reported experience with oximetry.

Methods

The study design, patient demographic data, and data validation are described in part I (the accompanying article).[12] In brief, the study was designed as a multiinstitutional randomized trial with two groups of patients. Candidates for the study were all inpatients able to provide informed consent, 18 yr of age or older, who were scheduled for elective or emergency operations that requiring general, spinal, epidural, or axillary anesthesia, which was expected to last more than 20 min. Patients scheduled for neurologic, cardiac, or outpatient procedures were excluded from the study. Those scheduled for elective surgery were assigned to an OR the day before surgery, and then the pulse oximeters were assigned randomly to a room. The random assignment of an individual patient could not be changed by moving the patient to another room. For emergency cases, an envelope containing the random assignment was drawn from a stack. Patients assigned a pulse oximeter (oximeter group) were monitored from just before induction of anesthesia until their discharge from the PACU. The control group was not monitored with an oximeter at any time. The preoperative visit, premedication, anesthesia, monitoring other than pulse oximetry, observation, recovery, and other anesthesia and PACU related care followed the routine guidelines of each institution. Data relevant to anesthesia care were documented by anesthesia personnel or PACU staff on a special form. Information about OR and PACU events were selected from a list of 42 items.[12] The OR and PACU events were defined as "an unanticipated, undesirable incident that required intervention and did or could cause morbidity." Operational definitions for potentially ambiguous events were stated on the form or in a separate manual available to the anesthetists and PACU staff at all times.

Specially trained nurse anesthetists and medical students, blinded to the experimental grouping, recorded information about any postoperative complication and intervention on a special form on the day of discharge from the hospital or at the latest, the seventh postoperative day. If, at the time this information was recorded, a patient experienced a complication, data collection continued until discharge or complete recovery. Operational terms for complications that were potentially ambiguous were defined on the form or in a manual available to all who collected data for the study.[12]

At the completion of the study, before any results were available, a 28-item questionnaire was distributed to all anesthesiologists (M.D.s) to evaluate changes in practice habits, changes in patient care, and experiences with and opinions regarding the impact of pulse

oximetry monitoring on peri- and postoperative complications. All questionnaires were anonymous.

For the statistical analysis, the response variables were grouped first into OR events, PACU events, and postoperative complications related to either the respiratory, cardiovascular, neurologic, or other incidents. These were tested first with chi-square test and second, by stratification and multiple logistic-regression analysis to assess the value of pulse oximetry in coherence with other independent variables and to determine the influence of intergroup differences (confounders) in the study population. After this, the individual events (*e.g.*, hypotension) within each main group (*e.g.*, cardiovascular) were examined one by one using a chi-square test controlled with logistic-regression analysis for all significant findings. Changes in patient care were tested with the chi-square test. A P value < 0.05 was considered statistically significant. The significant P values are reported to enable the reader to calculate further adjusted levels of significance taking multiple comparisons into account. The text or footnotes indicate where intergroup differences (confounders) affected the P value for complications.

Results

The study population consisted of 20,802 patients from five hospitals randomly assigned to one of two groups; 10,312 to the oximetry group and 10,490 to the control group. In general, background variables, such as demographic data, patient factors, and type of anesthesia, were distributed evenly, except for age, duration of surgery, some types of surgery, and some types of anesthesia, which differed slightly but significantly.[12]

Events in the OR and in the PACU

During anesthesia, the incidence rate of one or more respiratory events was 11.2% with oximetry and 3.3% without ($P < 0.00001$); this difference resulted from the 19-fold increase in the diagnosis of hypoxemia in the oximetry group (table 1). An equally significant increase in the detection of respiratory events in the oximetry group occurred in the PACU, with a similar 19-fold increase in the rate of detected hypoxemia (table 2). In the OR and PACU, an increased detection of hypoventilation, endobronchial intubation, broncho-

Table 1. Respiratory and Cardiovascular Events during Anesthesia

Event	Control (n = 10,490)		Oximetry (n = 10,312)		
	N	%	N	%	P*
Respiratory					
Hypoxemia	41	0.4	818	7.9	<0.00001
Hypoventilation	43	0.4	126	1.2	<0.00001
Airway obstruction	29	0.3	44	0.4	NS
Laryngospasm	20	0.2	24	0.2	NS
Bronchospasm	66	0.6	85	0.8	NS
Aspiration (suspected)	10	0.1	13	0.1	NS
Difficulty with intubation	139	1.3	170	1.7	NS
Esophageal intubation	31	0.3	38	0.4	NS
Endobronchial intubation	5	0.05	27	0.3	<0.001
Reintubation	20	0.2	16	0.2	NS
Other	31	0.3	18	0.2	NS
Total no. of patients with 1 or more event(s)	351	3.3	1155	11.2	<0.00001
Cardiovascular					
Hypotension	469	4.5	456	4.4	NS
Hypertension	224	2.1	216	2.1	NS
Hypovolemia	39	0.4	56	0.5	NS
Arrhythmia (all)	197	1.9	188	1.8	NS
Cardiac arrest with resuscitation	11	0.1	4	0.04	NS
Myocardial ischemia	26	0.2	12	0.1	<0.03
Other	14	0.1	10	0.1	NS
Total no. of patients with 1 or more event(s)	804	7.7	808	7.8	NS

* Chi-square test followed by stratification and logistic regression analyses to control for the known confounders.

Table 2. Respiratory, Cardiovascular, and Neurologic Events in the Postanesthesia Care Unit

Event	Control (n = 9772)* N	Control (n = 9772)* %	Oximetry (n= 9578)* N	Oximetry (n= 9578)* %	P†
Respiratory					
Hypoxemia	70	0.7	1316	12.8	<0.00001
Hypoventilation	76	0.8	187	2.0	<0.00001
Hypercapnia	47	0.5	55	0.6	NS
Airway obstruction	12	0.1	23	0.2	NS
Bronchospasm	10	0.1	22	0.2	<0.03
Atelectasis	2	0.02	11	0.1	<0.02
Reintubation	10	0.1	4	0.04	NS
Other	26	0.2	22	0.2	NS
Total no. of patients with 1 or more event(s)	180	1.7	1477	14.3	<0.0001
Cardiovascular					
Hypotension	83	0.9	95	1.0	NS
Hypertension	56	0.6	61	0.6	NS
Hypovolemia	17	0.2	18	0.2	NS
Arrhythmia (all)	47	0.4	63	0.6	NS
Bradycardia	21	0.2	37	0.4	<0.003
Cardiac arrest with resuscitation	3	0.03	4	0.04	NS
Myocardial ischemia	8	0.08	5	0.05	NS
Other	6	0.06	8	0.08	NS
Total no. of patients with 1 or more event(s)	185	1.8	227	2.2	<0.02
Neurologic					
Postoperative coma	6	0.06	1	0.01	NS
Prolonged emergence	57	0.6	56	0.6	NS
Other	19	0.2	10	0.1	NS

* The number of patients is lower than in the operating room because some of the patients were transferred to the intensive care unit or directly to the ward.

† Chi-square test followed by stratification and logistic regression analysis to control for the known confounders.

spasm, and atelectasis in the oximetry group was linked with the increased detection of hypoxemia (tables 1 and 2).

The oximetry group had a 7.8% rate of at least one cardiovascular event, and the control group had a 7.7% rate (difference not significant). Signs of myocardial ischemia were detected in the OR in 12 patients in the oximeter group and in 26 in the control group ($P < 0.03$). Multiple logistic-regression analysis confirmed that the reduction in the incidence of myocardial ischemia indicators was associated with pulse oximetry monitoring. All other cardiovascular events during anesthesia were distributed evenly (table 1). In the PACU, more cardiovascular events were detected in the oximeter group than in the control group (2.2% *vs.* 1.8%, $P < 0.02$), which was a result of bradycardias being diagnosed almost twice as often in the oximeter group as in the control group (table 2). The number

Table 3. Duration of Anesthesia and PACU Stay, and Time to Orientation as to Person, Time, and Place

	Control (n = 10,490) Mean	Median	Range	Oximetry (n = 10,312) Mean	Median	Range	P
Duration of anesthesia (min)	118.5	105	9.0–870	122.5	105	8–755	<0.0002*
Duration of PACU stay (min)	165.9	115	0–1440†	179.6	120	0–1440†	<0.00001
Time to orientation as to person, time, and place (min)	32.6	5	0–1440†	35.7	5	0–1440†	NS

PACU = postanesthesia care unit.

* Nonsignificant when controlling for the fact that duration of surgery was longer in the oximetry group than in the control group.[12]

† After 24 h the patients were transferred to the intensive care unit if not ready to be discharged to the ward.

of all other OR and PACU events, including neurologic events, was similar in the two groups. The two groups did not significantly differ (in relation to the type of anesthesia) by time of reorientation to person, time, and place in the PACU (table 3).

Changes in Patient Care

In the OR, treatment with antagonists (opioid and neuromuscular) beyond the department's standard requirements was not affected by pulse oximetry. In the PACU, 51 (0.5%) control patients and 91 (0.9%) oximeter-monitored patients ($P < 0.02$) received naloxone. During anesthesia, the number of patients in which at least one arterial blood sample was drawn totaled 1,972 (9.5%); 1,001 in the oximeter group and 971 in the control group (difference not significant). The number of arterial blood samples drawn in the individual patient was equal in both groups with no change over time. A similar pattern was found in the PACU. The length of stay in the PACU was longer for patients in the oximeter group than in the control group (table 3). The flow rate of supplemental oxygen given in the PACU was significantly greater in the oximeter group, with 6.5% of the oximeter-monitored patients receiving more than 3 L/min of oxygen compared with 2.8% of the control patients ($P < 0.00001$). The number of patients discharged from the PACU with an order for supplemental oxygen was 1,276 (13.3%) in the oximeter group and 343 (3.5%) in the control group ($P < 0.00001$).

In 10.5% of the patients in the oximeter group, the anesthetist stated that the reading from the oximeter prompted one or more changes in the treatment of the patients in the OR. A poorer American Society of Anesthesiologists physical status was associated with a significant increase in the rate of intervention ($P < 0.00001$, fig. 1). In the PACU, the staff stated that treatment was changed one or more times in 17.2% of the patients as a result of the oximeter readings, which also was correlated significantly with the patient's physical status (fig. 1).

Postoperative Complications

The total number of patients in whom at least one postoperative complication was identified was 1,030 (10%) with pulse oximetry and 985 (9.4%) without (difference not significant). Although more respiratory complications were identified with oximetry than without it ($P < 0.05$, by primary analyses with chi-square test), the two groups did not differ in their incidence of cardiovascular, neurologic, infectious, or miscellaneous complications (table 4). Furthermore, when confounding factors were controlled with multiple logistic-regression analysis, the groups did not differ significantly by the rate of respiratory complications either (table 4). The significance level was not affected when the number of all the other complications was controlled against the known confounders.

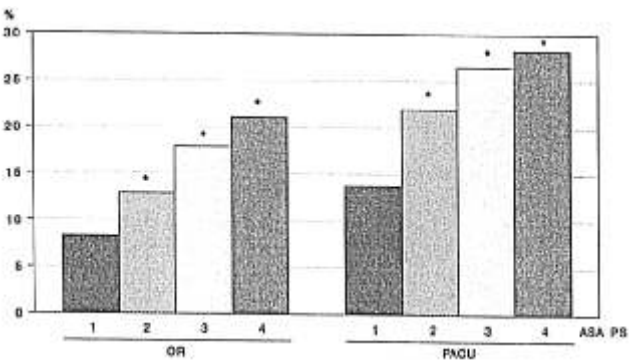

Fig. 1. Change in patient care (percent on the ordinate) in different American Society of Anesthesiologists physical status categories as a consequence of the oximeter readings in the operating room (n = 10,312) and postanesthesia care unit (n = 9,578). *A significantly higher rate of change was found in patient care with poorer patient physical status ($P < 0.00001$).

The percentage of patients treated in the intensive care unit was 2.1% with oximetry and 1.6% without it ($P < 0.008$). After controlling for confounders, the incidence of postoperative complications did not differ statistically between the two groups for any specific risk category, *e.g.*, emergency cases, or patients with an ASA physical status of III or IV. The duration of hospitalization was a median of 5 days in both groups, and 90% of the patients in both groups were discharged within 15 days. An equal number of inhospital deaths occurred in the two groups, 1.1% in the oximeter group and 1.0% in the control group. Between these, a total of seven deaths were classified as possibly anesthesia related: three deaths in the oximetry group and four in the control group. The seven deaths did not display any specific pattern.

Questionnaires

Questionnaires were returned by 104 anesthesiologists (73%, table 5). In 14 cases, anesthesiologists reported that serious complications possibly were prevented by using pulse oximetry. These were esophageal intubations not detected by auscultation (n = 4), disconnections or tracheal tube displacements during surgery (n = 3), human error with serious hypoventi-

Table 4. Postoperative Complications

Complication	Control (n = 10,490) N	%	Oximetry (n = 10,312) N	%	P*
Respiratory					
Pneumonia	168	1.6	169	1.6	NS
Atelectasis	74	0.7	101	1.0	NS†
Respiratory insufficiency	229	2.2	279	2.7	NS†
Requiring mechanical ventilation	83	0.8	115	1.1	NS†
Requiring CPAP	107	1.2	127	1.2	NS
Total‡	334	3.2	394	3.8	NS†
Cardiovascular					
Cardiac failure	65	0.6	71	0.7	NS
Myocardial infarction	18	0.2	14	0.1	NS
Angina pectoris	6	0.06	5	0.05	NS
Pulmonary embolism	20	0.2	12	0.1	NS
Cardiac arrest with resuscitation	12	0.1	8	0.08	NS
Arrhythmia	65	0.6	59	0.6	NS
Hypovolemia	99	0.9	93	0.9	NS
Hypotension	66	0.6	81	0.8	NS
Requiring inotropic support	37	0.4	44	0.4	NS
Hypertension	27	0.3	35	0.3	NS
Total‡	282	2.7	297	2.9	NS
Neurologic					
Coma	6	0.1	11	0.1	NS
Protracted confusion	65	0.6	62	0.6	NS
Stroke	19	0.2	13	0.1	NS
Total‡	113	1.1	105	1.0	NS
Infectious					
Sepsis	35	0.3	42	0.4	NS
Wound infection	114	1.1	128	1.2	NS
Peritonitis	4	0.04	11	0.1	NS
Total‡	518	4.9	556	5.4	NS

CPAP = continuous positive airway pressure.

* Chi-square test followed by stratification and stepwise logistic regression analyses to control for the known confounders.

† Primary analyses indicated $P < 0.05$, but when controlling for the confounding factors by stratification and logistic regression analyses (age, duration and type of surgery, and type of anesthesia), no statistically significant difference existed concerning this variable.

‡ A patient may have more than one complication.

lation of the patient (n = 1), anesthesia machine failures (one in which oxygen was discontinued completely although no alarm was activated, n = 3), and serious respiratory problem immediately after extubation (n = 3). One anesthesiologist experienced a situation in which a false oximeter reading and subsequent alarm resulted in a reaction posing potential risk to the patient; unfortunately, the incident was not described in detail. The anesthesiologists stated overall that with the use of pulse oximeters in the OR and PACU, their work was easier (58%), unaffected (40%), or impeded (2%).

Discussion

The results of this randomized evaluation demonstrate that pulse oximetry improves the anesthesiologist's ability to detect hypoxemia and related events in the OR and PACU and that the use of the oximeter was associated with a significant decrease in the rate of myocardial ischemia. Pulse oximetry monitoring prompted several changes in OR and PACU care, but the postoperative complication rates were not reduced.

The 19-fold increase in the detection rate of hypoxemia in the OR and PACU can be understood easily. When only one of the study groups has the equipment to measure oxygen saturation, inevitably, more cases of hypoxemia will be identified. It is well known from studies as early as the 1940s that hypoxemia is difficult to detect from clinical signs alone.[13] From our previous observational studies, we know that 75% and 95% of hypoxemic episodes were undetected in the OR and PACU, respectively.[14,15] In the OR, 53%, and in the PACU, 55% of these patients had one or more episodes of mild hypoxemia with an oxyhemoglobin saturation of 86–90%. Severe hypoxemia with an oxyhemoglobin saturation below 81% was observed in 20% of patients in the OR and 13% in the PACU.[14,15] The findings in

Table 5. Questionnaire Response Form 104 Anesthesiologists

Questions	Yes (%)
Has this pulse oximetry study changed your general patient care?	54
Did a situation(s) occur in which an oximeter was particularly helpful in guiding clinical management?	94
Did a situation(s) occur during the study in which you think pulse oximetry helped to avoid a serious event/complication?	18
Did a situation(s) occur in which an oximeter gave a false reading to which you reacted with potential risk to the patient, *i.e.*, extubated the patient, gave medication?	1
Do you consider that the routine use of pulse oximetry in the OR will reduce the rate of some undesired events/complications during anesthesia?	83
Do you consider that the routine use of pulse oximetry in the PACU will reduce the rate of some undesired PACU events/complications?	92
Do you consider that the routine use of pulse oximetry in the OR and PACU will reduce the rate of some postoperative complications in the ward?	66
Do you feel more secure when using a pulse oximeter?	80

OR = operating room; PACU = postanesthesia care unit.

another study, which also used continuous measurement of oxyhemoglobin saturation during postoperative recovery, supported our results.[16] Our earlier randomized blinded study indicated that pulse oximetry monitoring reduced the incidence, severity, and duration of hypoxemia in the OR and PACU.[9] Results in children supported this finding.[7,8] Consequently, in the current study, we suspect that the occurrence of hypoxemia in the control group was actually several times more frequent than the reported rate (tables 1 and 2) and probably substantially higher still than in the oximetry group.

In a previous prospective but not randomized study, more episodes of hypoxemia were not detected when oximeters were used in the ORs.[10] The incidence of hypoxemia in the OR was approximately equal to that in our control group (table 1). We attribute this discrepancy to the deliberately looser definition of events, including hypoxemia in that study. Specifically, to be reportable, an event must have been of sufficient severity to have some "impact" on care beyond the OR. This contrasted with our study in which specific relatively low numeric thresholds were set for hypoxemia.

The significant increase in the detection of hypoventilation, endobronchial intubation, bronchospasm, and atelectasis in the oximetry group in the OR and PACU often was linked to the detection of hypoxemia (tables 1 and 2). Whenever a patient experienced hypoxemia, the anesthetist or PACU staff member would seek a clinical explanation, which was noted for only 15% of oximeter-monitored patients with hypoxemia but still was significantly more frequent than for the control group (tables 1 and 2). This result was consistent with the findings from one of our previous studies in which a specially trained observer was unable to find an obvious clinical reason for 76% of the hypoxemic episodes.[15]

In the OR, the overall number of cardiovascular events was unaffected, but myocardial ischemia occurred less in the oximetry group than in the control group (table 1). Our study was not designed to look specifically for myocardial ischemia; however, the anesthesiologist reported ischemia when detecting ST segment depression on the electrocardiographic monitor or, in awake patients under regional anesthesia, when the patient complained of typical chest pain. If this did not occur by chance, it suggests an association between hypoxemia, as defined by pulse oximetry, and myocardial ischemia. We know that myocardial ischemia can be asymptomatic and can exist without ST segment depression detected by ordinary monitoring equipment. Therefore, we probably did not identify many ischemic events. Possibly related to myocardial ischemia were the cardiac arrests, of which there were almost threefold as many in the control group as in the oximetry group; however, this difference was not statistically significant. The relationship between hypoxemia and myocardial status also was highlighted in another study of pulse oximetry in the OR.[17] The introduction of pulse oximetry significantly reduced the rate at which patients (not prescheduled to go to the intensive care unit) were admitted to the unit to exclude myocardial infarction.

In our study, the total rate of hypotension in the OR was similar to that in a study by Cooper *et al.*[10] and by Cohen *et al.*[18] of 112,000 anesthetic procedures. But, unlike the result in the Cooper *et al.*[10] study, we did not observe a reduced incidence of hypotension and hypovolemia during oximetry monitoring in the OR (table 1). The total rate of cardiovascular events in the PACU was higher in the oximetry group as a consequence of the significantly increased detection of bradycardia (table 2) facilitated by the pulse oximeter. In the control group, only high-risk patients and those with known cardiovascular disease were monitored with continuous electrocardiography in the PACU, and thus, many bradycardic events may have remained undetected.

As a consequence of the monitoring, several changes in patient care in the PACU resulted. The increased flow rate of supplemental oxygen in the PACU and the increase in number of patients discharged from the PACU with supplemental oxygen corroborated the results of our previous observational study in the PACU in which 22% of the patients had unrecognized oxyhemoglobin saturation ($\leq$ 90%) at discharge.[15] We believe that, in our study, the higher number of oximetry-monitored patients treated with naloxone in the PACU was another example of how the oximeter readings identified a problem to which the staff reacted.

Why then was a reduction in postoperative complications not achieved with pulse oximetry in the current study? A deficient study design or a learning effect are two possible factors. Did the study design allow us to detect a true difference? The probability of type II error (β, the probability of accepting the null hypothesis when the alternative hypothesis is true) was 0.2% for the overall number of postoperative complications, 10% for the cardiovascular, and 6% for the respiratory complications. This agreed well with the required

minimum statistical power of 90% (β maximum, 10%) established in the design of the trial.[12] If we had included a larger sample size, myocardial infarction (1 in 650 patients) or perhaps even possible anesthesia-contributory death (1 in 3,365 patients) could have been used as an outcome variable. The required sample size based on these two variables would have been approximately 500,000 and 1,900,000 patients, respectively, to observe a reduction in the complication and death rates of 25%, with 2α at 5% and a minimum power of 90%. In large multiinstitutional studies of variables with low rates, unknown confounding elements can be controlled only by proper randomization. We believe that the randomization in this study was successful, but if the result of the intervention by pulse oximetry was small, several unknown confounders and bias would be able to blur a small difference between the groups. But, overall, it appears to us that there was sufficient statistical power and randomization to conclude that pulse oximetry does not decrease the incidence of early (up to 7 days) postoperative complications. This does not address the question of rarer events, *e.g.*, myocardial infarction, serious neurologic injury, or anesthesia-contributory death, for which this study had an insufficient sample size. The figures of myocardial infarction or even anesthesia-contributory death might be different in high-risk patients. For example, had we excluded from the study all patients not requiring general anesthesia and all patients without any evidence of cardiovascular disease, 20,000 patients might have been ample to show an effect of pulse oximetry on the outcome variables we examined. Our study was not able to and not designed to confirm the findings in the American Society of Anesthesiologists Closed Claims Study and other recent safety studies, which indicate that a number of anesthetic mishaps may be preventable by increased monitoring, *i.e.*, by pulse oximetry, because these studies concerned only serious events, nearly all resulting in serious disability or death.[19–22]

Was there a learning effect? The long study period of this trial could have been responsible for a learning effect that led to improvements in care even when the pulse oximeter was not available. In the questionnaire, 54% of the anesthesiologists stated that they had changed their routine of care as a consequence of the study. However, the number of events, including hypoxemia and complications, was stable in both groups during the study.[12] Staff training and knowledge of how to react to pulse oximetry readings also could have influenced our results. To minimize this effect, the staff were trained at the start of the study. We do not know if this completely prevented a learning effect. We lack evidence that a learning effect obscured a difference in complication rates between the two groups.

There was a large contrast between the objective results of this study and the subjective opinions of the participating anesthesiologists (table 5) regarding the usefulness of pulse oximetry. Perhaps the 66% of anesthesiologists who believe that routine pulse oximetry monitoring will reduce the rate of postoperative complications are correct, but this could not be demonstrated in this sample of 20,802 patients with the chosen variables. Perhaps the anesthesiologists are referring to the more serious, rarer events that would require an impractically large sample population for a study to achieve sufficient statistical power. No one doubts that oxygenation of the patient's blood is essential and that pulse oximetry assists in assessing the degree of oxygenation and maintaining it within a physiologic band. In that sense, pulse oximetry joins sphygmomanometry, electrocardiography, and respirometry as monitors of "vital signs" that anesthesiologists attempt to keep within physiologic limits. For each of these variables, there exist ranges that are incompatible with good health or even survival. Many anesthesiologists and the clinicians involved in this study apparently recognize pulse oximetry as one of the tools to assess the quality of care, namely the ability to maintain a patient within the physiologic limits that are generally considered to reflect good health. In the framework of the model of accident evolution described by Gaba,[23] pulse oximetry, by reducing the incidence and severity of hypoxic episodes, reduces the likelihood that one or more critical events will occur concurrently with hypoxia. This should reduce the possibility of a correctable problem causing an irreversible injury. Perhaps anesthesiologists intuitively have accepted such a mechanism for the effectiveness of pulse oximetry to prevent rare events, as evidenced by the widespread demand for pulse oximetry in so many countries. Unfortunately, we have no measure of safety or how to gauge the allowable margin for error.

In conclusion, the study confirmed that pulse oximetry can detect hypoxemia and related events and thus facilitate its correction. In many instances, the mechanism of the hypoxemia was not obvious, but the clinician was made aware that treatment of hypoxemia was indicated. The reduction of the incidence of myocardial ischemia highlights the likely important role of

pulse oximetry. Despite these successes of pulse oximetry, it did not affect the eventual outcome of anesthesia; thus, our main hypothesis was not confirmed. Must we conclude that pulse oximetry should be rejected or reserved for selected patients? We think not. We assume that a similar assessment of other monitors also would yield data that would allow flexible interpretations. The decisions about pulse oximetry and the employment of many other monitors, however, rest on many factors in addition to the scientific demonstration of utility in a selected patient population.[24]

The conflicting subjective and objective results of the current study, despite an intense, methodical collection of data from a relatively large population, confirms that measuring the effectiveness of interventions to reduce rare, but important events is practically difficult. Improved methods for evaluation of new standards and monitoring equipment are needed if we are to rely upon more than intermediate outcome measures and subjective assessments to judge the effectiveness of implementing costly practices and technologies.

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References

1. Yelderman M, New W: Evaluation of pulse oximetry. ANESTHESIOLOGY 59:349–352, 1983

2. Tremper KK, Barker SJ: Pulse oximetry. ANESTHESIOLOGY 70:98–108, 1989

3. Kelleher JF: Pulse oximetry. J Clin Monit 5:37–62, 1989

4. Fanconi S: Pulse oximetry for hypoxemia: A warning to users and manufacturers. Intensive Care Med 15:540–542, 1989

5. Ralston AC, Webb RK, Runciman WP: Potential errors in pulse oximetry: I. Pulse oximeter evaluation. Anaesthesia 46:202–206, 1991

6. Webb RK, Ralston AC, Runciman WB: Potential errors in pulse oximetry: II. Effects of changes in saturation and signal quality. Anaesthesia 46:207–212, 1991

7. Coté CJ, Goldstein A, Coté MA, Hoaglin DC, Ryan JF: A single-blind study of pulse oximetry in children. Anesth Analg 601:46–51, 1988

8. Coté CJ, Rolf N, Liu LMP, Goudsouzian NG, Ryan JF, Zaslavsky A, Gore R, Todres D, Vassallo S, Polander D, Alifimoff JK: A single blind study of combined pulse oximetry and capnography in children. ANESTHESIOLOGY 74:980–987, 1991

9. Moller JT, Jensen PF, Johannessen NW, Espersen K: Hypoxemia is reduced by pulse oximetry monitoring in the operating room and in the recovery room. Br J Anaesth 68:146–150, 1992

10. Cooper JB, Cullen DJ, Nemekkal R, Hoaglin DC, Gevirtz CC, Csete M, Venable C: Effects of information feedback and pulse oximetry on the incidence of anesthesia complications. ANESTHESIOLOGY 67:686–694, 1987

11. Keats AS. Anesthesia mortality in perspective. Anesth Analg 71:113–119, 1990

12. Moller JT, Pedersen T, Rasmussen LS, Jensen PF, Pedersen BD, Ravlo O, Rasmussen NH, Espersen K, Johannessen NW, Cooper JB, Gravenstein JS, Chraemmer-Jørgensen B, Wiberg-Jørgensen F, Djernes M, Heslet L, Johansen SH: Randomized evaluation of pulse oximetry in 20,802 patients: I. Design, demography, pulse oximetry failure rate, and overall complication rate. ANESTHESIOLOGY 78:436–444, 1993

13. Comroe JH, Botelho S: The unreliability of cyanosis in the recognition of arterial anoxemia. Am J Med Sci 214:1–6, 1947

14. Moller JT, Johannessen NW, Berg H, Espersen K, Larsen LE: Hypoxaemia during anaesthesia: An observer study. Br J Anaesth 66: 437–444, 1991

15. Moller JT, Wittrup M, Johansen SH: Hypoxemia in the post-anesthesia care unit: An observer study. ANESTHESIOLOGY 73:890–895, 1990

16. Brown LT, Purcell GJ, Traugott FM: Hypoxemia during post-operative recovery using continuous pulse oximetry. Anaesth Intensive Care 18:509–516, 1990

17. Cullen DJ, Nemeskal AR, Cooper JB, Zaslavsky A, Dwyer MJ: The effect of pulse oximetry, age and ASA physical status on the frequency of patients unexpectedly admitted to a postoperative intensive care unit and the severity of their anesthesia related complications. Anesth Analg 74:181–188, 1992

18. Cohen M, Duncan PG, Pope WDB, Wolkenstein C: A survey of 112,000 anaesthetics at one teaching hospital (1975–83). Can J Anaesth 33:22–31, 1986

19. Caplan RA, Ward RJ, Posner KL, Cheney FW: Unexpected cardiac arrest during spinal anesthesia: A closed claims analysis of predisposing factors. ANESTHESIOLOGY 68:5–11, 1988

20. Tinker JH, Dull DL, Caplan RA, Ward RJ, Cheney FW: Role of monitoring devices in prevention of anesthetic mishaps: A closed claims analysis. ANESTHESIOLOGY 71:541–546, 1989

21. Eichhorn JH: Prevention of intraoperative anesthesia accidents and related severe injury through safety monitoring. ANESTHESIOLOGY 70:572–577, 1989

22. Caplan RA, Posner KL, Ward RJ, Cheney FW: Adverse respiratory events in anesthesia: A closed claims analysis. ANESTHESIOLOGY 72:828–833, 1990

23. Gaba DM: Human error in anesthetic mishaps. Int Anesthesiol Clin 27:137–147, 1989

24. Gravenstein JS: On the shoulders of progress. J Clin Monit 8: 191–192, 1992