Pulse Oximetry for Perioperative Monitoring: Systematic Review of Randomized, Controlled Trials

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Monitoring with pulse oximetry might improve patient outcome by enabling an early diagnosis and, consequently, correction of perioperative events that might otherwise cause postoperative complications or even death. The aim of the study was to clarify the effect of perioperative monitoring with pulse oximetry and to identify the adverse outcomes that might be prevented or improved by its use. Trials were identified by computerized searches of the Cochrane Library, MEDLINE, EMBASE, and by checking the reference lists of trials and review articles. All controlled trials that randomized patients to either pulse oximetry or no pulse oximetry during the perioperative period, including in the operating and recovery room, were included in the study. The search identified six reports. Of these 6 reports, 4 studies with data from 21,773 patients were considered eligible for analysis. Two studies specifically addressed the outcomes in question; both found no effect on the rate of postoperative complications using perioperative pulse oximetry. Hypoxemia was reduced in the pulse oximetry group both in the operating room and in the recovery room. During observation in the recovery room, the incidence of hypoxemia in the pulse oximetry group was 1.5–3 times less. There were postoperative complications in 10% of the patients in the oximetry group and in 9.4% in the control group. The duration of hospital stay was a median of 5 days in both groups, and an equal number of in-hospital deaths was registered in both groups. The studies confirmed that pulse oximetry could detect hypoxemia and related events. However, given the relatively small number of patients studied and the rare events being sought, the studies were not able to show an improvement in various outcomes.

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The introduction of the pulse oximeter, a clinical monitor of oxygen saturation and pulsation, has made it possible to monitor perioperative hypoxemia with a noninvasive continuous measuring technique (1). The main value of pulse oximetry is the ability to provide an early warning of hypoxemia. For the individual patient, it is unpredictable at which level of hypoxemia the brain, heart, and other organs will suffer and to what extent irreversible damage may occur. Many factors such as cardiac output, hemoglobin concentration, and oxygen demand can affect the smallest tolerable value of oxyhemoglobin saturation (2). The occurrence and possible pathogenesis of perioperative hypoxemia were first described many years ago (3,4).

Monitoring with pulse oximetry might improve patient outcome by enabling an early diagnosis and, consequently, correction of perioperative events that might cause postoperative complications or even death (5). An operational definition of an event is an undesirable incident that required intervention and did or could cause complications or death. Such events may be attributed to pathophysiologic processes, to malfunction of gas supply or equipment, or to human error, e.g., esophageal intubation or anesthetic mismanagement (6). For many of these events, hypoxemia is probably the most common mechanism responsible for the eventual adverse outcomes (7). Therefore, the monitoring of perioperative oxygenation may improve a patient's outcome after anesthesia.

Two studies have suggested that hypoxemia in the operating room and recovery room is common and that monitoring with pulse oximetry permits its early diagnosis and treatment (8,9). Thus, pulse oximetry can reduce the incidence and severity of hypoxemia.

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Only a few randomized clinical trials of pulse oximetry have been performed during anesthesia and in the recovery room that describe perioperative hypoxemic events, postoperative cardiopulmonary complications, and cognitive dysfunction (9–12).

We conducted a systematic review of randomized, controlled trials to clarify the real effect of perioperative monitoring with pulse oximetry and to identify the adverse outcomes that might be prevented or improved by the use of this technique. The following hypotheses were tested: The use of pulse oximetry is associated with an improvement in the detection and treatment of hypoxemia, and the use of pulse oximetry *per se* reduces morbidity as well as mortality in the perioperative period.

Methods

Randomized, controlled trials were identified by searching MEDLINE (1966 to 2001), EMBASE (1980 to 2001), The Cochrane Anaesthesia Review Group's specialized register, and The Cochrane Library 2001, issue 3. The bibliography of each article was scanned for relevant references. Studies published in any language were considered.

Studies included in the systematic review had to fulfill the following criteria: all had to be randomized or quasi randomized, controlled trials dealing with the use of pulse oximetry or no pulse oximetry during the perioperative period, including the operating and recovery room; trials were included irrespective of their blinding, number of patients randomized, or the language of the article; and the types of participants were patients 18 yr of age or older undergoing surgery with anesthesia.

The following data on randomization and blinding procedure was extracted: (a) number of randomized patients, (b) number of patients not randomized and the reasons for this, (c) exclusion after randomization, (d) dropouts, and (e) blinding of patients and observer.

The end points for analysis were:

1. Events detectable by pulse oximetry: hypoxemia (Spo_2 <90% corresponding to an arterial oxygen tension <60 mm Hg).
2. Causes of events: patient respiratory causes of hypoxemia (pneumothorax, bronchospasm, air embolus, respiratory depression, apnea, airway obstruction, pneumonia, ventilatory failure, and pulmonary embolus), patient mechanical causes of hypoxemia (esophageal or main stem intubation, mucus plug, or kinked endotracheal tube), and delivery system causes of hypoxemia (anesthesia machine and gas supply problems).
3. Interventions that may prevent, attenuate, or shorten these events are airway support, endotracheal intubation, manual or mechanical ventilation, oxygen treatment, pressors and inotropes, and fluid treatment.
4. Any serious complications that occur during anesthesia or in the postoperative period (postoperative intensive care admittance because of respiratory insufficiency, circulatory insufficiency, or infections). These were defined as follows: respiratory insufficiency—pneumonia (fever, chest radiograph, or positive culture), atelectasis (chest radiograph), pneumothorax (diagnosed on chest radiograph), respiratory insufficiency (requiring intervention), cardiovascular insufficiency (cardiac arrest, cardiac failure, or myocardial infarction), renal and hepatic insufficiency, neurologic and cognitive dysfunction measuring memory function with the Wechsler memory scale, and serious infection requiring antibiotics.
5. Intra- or postoperative mortality.
6. Duration of recovery or intensive care stay.

The principal outcome measures are postoperative complications and mortality from all causes, assessed at the end of the follow-up period scheduled for each trial.

The methods and adequacy of randomization, blinding of the study, and description of withdrawals were considered in the quality assessment. Successful randomization was defined as adequate measures taken to conceal allocation (e.g., central randomization, serially numbered, and opaque, sealed envelopes or another description that contained elements convincing of adequate concealment).

The data were combined quantitatively using Review Manager 4.1 (Cochrane Collaboration). We tested the outcome variables in two-way tables (two-tailed χ^2 or Fisher's exact tests). Mean differences with 95% confidence intervals were used for analyzing continuous variables. For dichotomous variables, rate differences with their 95% confidence intervals were calculated.

Results

Searching yielded six reports. Of those six reports, two were judged ineligible for analysis (6,13) because they either had no control group or they lacked information on the relevant postoperative outcomes. All outcome measures in the included studies were extracted and can be seen in detail in Table 1. The types of outcome measures were separated into events detectable by pulse oximetry that could result in complications and perioperative complications detected otherwise. The included studies used a number of different ways of assessing postoperative outcome:

Table 1. Details of the Randomized, Controlled Trials of Pulse Oximeter Monitoring Versus No Pulse Oximeter Monitoring in the Perioperative Period

Authors	Methods	Patient no.	Outcomes
Bierman et al. 1992 (14)	Blinded, control group	20/15	Clinically unapparent desaturation[a]
Moller et al. 1992 (15)	Blinded, control group	100/100	Hypoxemia in the recovery room[b]
Moller et al. 1993 (17)	Quasi randomized, blinded comparison	358/378	Postoperative cognitive dysfunction[c]
Moller et al. 1993 (18)	Quasi randomized	10,312/10,490	Postoperative complications: respiratory, cardiovascular, neurologic, and infectious

[a] Clinically undetected episodes of desaturation for more than 1 min.
[b] Saturation < 85% for more than 30 s during the recovery period.
[c] Problems with recent memory (telephone numbers, appointments, and so on).

1. Events with hypoxemia measured either with blood gas analyses or pulse oximetry (two trials).
2. Tests of cognitive function: Wechsler memory scale, continuous reaction time, and subjective perception of cognitive dysfunction (test of memory) (one trial).
3. Clinical outcome: respiratory, cardiovascular, and neurologic complications after anesthesia (one trial).

Studies Using Blood Gas Analysis and Pulse Oximetry Assessing Hypoxemia

In the Bierman et al. (14) study (Group 1), the staff was instructed to use the pulse oximetry data in lieu of arterial blood gas analysis whenever possible. The desaturation alarm on the oximeters was set to sound at values less than or equal to 93%. For patients in Group 2, blood gas analyses were obtained every hour or more frequently as was clinically indicated. These patients were monitored with a modified pulse oximeter from which Spo_2 was recorded continuously at a distant site but not displayed at the patients' bedside. The alarms for desaturation and pulse rate were deactivated in the bedside unit. The use of pulse oximetry allowed a significant reduction in arterial blood gases without any adverse events. Clinically inapparent desaturations were detected in 7 of 15 patients in the group without pulse oximetry in comparison with none detected in the pulse oximetry group. There was no difference in the number of changes in ventilatory support per postoperative intensive care unit stay between the two groups, whereas the dose of supplemental oxygen was adjusted more frequently in the group without pulse oximetry. There was no evidence of a significant difference between groups regarding duration of postoperative mechanical ventilation or intensive care unit stay.

Moller et al. (15) found that hypoxemia was reduced in the pulse oximetry group both in the operating room and in the recovery room (Table 2). During observation in the recovery room, the incidence of hypoxemia in the pulse oximetry group was 1.5–3 times less than in the group without pulse oximetry. No patient in the pulse oximetry group experienced extreme or severe hypoxemia.

As a consequence of the pulse oximetry monitoring, changes in the recovery room resulted in several interventions. For example, in the recovery room, on average, the patients in the oximeter group received an increased fraction of inspired oxygen; more patients in this group received naloxone, and the patients had a longer stay (16). The number of patients discharged from the recovery room with an order for supplemental oxygen was 13.3% in the oximeter group and 3.5% in the control group.

Study Using Tests of Cognitive Dysfunction

Moller et al. (17) demonstrated that postoperative cognitive function as measured by the Wechsler memory scale, and continuous reaction time was independent of perioperative monitoring with pulse oximetry. The postoperative subjective reports (by questionnaire) of cognitive deficits revealed no difference; 7% in the pulse oximetry group and 11% in the group without pulse oximetry believed that their cognitive abilities had decreased ($P < 0.06$) (Table 2). There was no significant difference in the two groups' ability to concentrate (10% versus 9%). The study showed no evidence of less postoperative cognitive impairment after perioperative monitoring with pulse oximetry.

Study Using Clinical Measures of Complications to Discharge

The study of Moller et al. (18), which included 20,802 surgical patients assigned to be monitored with pulse oximetry or not, found that one or more postoperative complications occurred in 10% of the patients in the oximetry group and in 9.4% in the control group. The two groups did not differ in cardiovascular, neurologic, or infectious complications; however, the incidence of respiratory complications was 3.8% in the pulse oximeter group compared with 3.2% in the control group (odds ratio, 1.21) (Table 2). The duration of hospital stay was a median of 5 days in both groups. An equal number of in-hospital deaths occurred in the

Table 2. Effect of pulsoximeter perioperative monitoring on postoperative hypoxemia and complications

Authors	Outcomes	Pulse oximeter group *n*/*N* (%)	Control group *n*/*N* (%)	Odds ratio (CI 95%)	Significance (*P*-value)
Bierman et al. 1992 (14)	Clinically undetected desaturation in intensive care unit	0/20 (0.0)	7/15 (46.7)	–	0.02
Moller et al. 1992 (15)	Hypoxemia in the recovery room	7/100 (7.0)	31/100 (31.0)	0.17 (0.07–0.40)	0.00007
Moller et al. 1993 (17)	Late cognitive dysfunction	24/345 (7.0)	41/374 (11.0)	0.61 (0.36–1.03)	0.06
Moller et al. 1993 (18)	Respiratory	394/10,312 (3.8)	334/10,490 (3.2)	1.21 (1.04–1.40)	0.01
	Cardiovascular	297/10,312 (2.9)	282/10,490 (2.7)	1.07 (0.91–1.27)	0.40
	Neurologic	105/10,312 (1.0)	113/10,490 (1.1)	0.94 (0.72–1.23)	0.70
	Infectious	556/10,312 (5.4)	518/10,490 (4.9)	1.10 (0.97–1.24)	0.14
	Total complications	1030/10,312 (10.0)	985/10,490 (9.4)	1.07 (0.98–1.17)	0.14

CI = confidence interval.

two groups: 1.1% in the oximeter group and 1.0% in the control group. Seven deaths were classified as possibly anesthesia related. Three deaths were in the oximetry group and four in the control group. The seven deaths did not display any specific pattern. A questionnaire, completed by the anesthesiologists, revealed that 18% of the anesthesiologists had experienced a situation in which a pulse oximeter monitor helped to avoid either a serious event or complication, and 80% of the anesthesiologists felt more secure when they used a pulse oximeter. Although monitoring with pulse oximetry prompted a number of changes in patient care, no evidence was found to indicate a significant reduction in the overall rate of postoperative complications using perioperative pulse oximetry.

Discussion

The studies confirmed that pulse oximetry can detect hypoxemia and related events. However, in our search, we were unable to find reliable evidence that pulse oximetry affects the outcome of anesthesia.

It is difficult to make a comparison between the overall rates of perioperative hypoxemia and postoperative complications in the present randomized studies because of the few study populations and differences in type of outcomes. It would seem that the present study's general rate of hypoxemia and complication are at the same level as other studies (12,19–22).

The positive effects of pulse oximetry monitoring, i.e., reduced extent of hypoxemia, ability to detect and correct potential harmful events, and the finding of several changes in patient care, contrast with the fact that no reduction in the number of postoperative complications was found (18). It is also worth emphasizing that patients monitored with pulse oximetry have no change in their outcome, despite the fact that they tend to be given more oxygen and naloxone (18) than patients monitored without pulse oximetry. This would suggest that merely increasing saturation levels from marginal to satisfactory is probably not going to make any difference in patient outcomes. In other words, the use of pulse oximetry as an early warning of moderate hypoxemia does not seem to be beneficial, even if the appropriate responses are instituted earlier than they would have been without pulse oximetry. This result conflicts with most anesthesiologists' beliefs. In the closed claims analyses of adverse respiratory events in anesthesia, reviewers judged that better monitoring would have prevented adverse outcomes in 72% of the claims (23,24). In the general analysis of the role of monitoring devices in the prevention of anesthetic mishaps, nearly 60% of the instances of death and brain damage were considered preventable by application of additional monitors. These studies exhibit a number of limitations including absence of a control group, a probable bias toward adverse outcomes, and reliance on data from direct participants rather than objective observers. The study of Moller et al. (18) has limitations. If they had involved more patients, perhaps they would have shown significant outcome differences (a type II error). The fact that the closed claims study came to different conclusions than the Moller et al. study might suggest power differences rather than lack of efficacy of the pulse oximeter. The study of rare events requires unusual methodology, and randomized, controlled trials may not

be an appropriate method of looking at outcome measures in a study of anesthetic complications.

The relationship between perioperative hypoxemia and impaired postoperative cognitive function has been debated (25). Moller et al. (17) found that 9% of the surgical patients thought that their mental function had deteriorated. In another study by Moller et al. (12), postoperative cognitive dysfunction in the elderly, as identified with neuropsychological tests, was present in 25.8% of patients one week after surgery and in 9.9% 3 months after surgery. However, hypoxemia was not a significant risk factor for cognitive dysfunction at any time. Perioperative monitoring with pulse oximetry did not seem to affect the patients' postoperative cognitive function.

Cognitive function tests are valuable when studying anesthetic drug effects; however, several patients have unexplained complaints of impaired cognitive function that are not verified by objective tests (12). One may speculate that application of a broader range of neuropsychological assessment than used in the study (12) could have detected varying deficits of an enduring nature. Using a broad range of tests, several investigators have described moderate to severe cognitive dysfunction lasting for several months after coronary bypass surgery (26).

The quality of blinding and allocation concealment of included studies was variable. Although pulse oximetry monitoring techniques were well standardized (6,13), the trials identified by our search did not use either correct randomized design or outcome variables. Because these studies could not address our review question, they were not included in our analysis. Furthermore, power analyses were seldom conducted to determine adequate sample sizes. Consequently, even the studies with high-quality blinding and allocation concealment may still not provide reliable results. No attempt has been made to weigh the results of different studies according to their methodological quality. Furthermore, we did not perform a meta-analysis because of the few studies, the different outcomes measured in the studies, and the heterogeneity in the studies.

The proliferation of monitors in anesthesia is obvious. The goals of monitoring as an adjunct to clinical decision-making is to directly or indirectly reduce the incidence of complications. This is based on the premise that unambiguous and accurate information, readily interpretable and available, will assist the anesthesiologist in deciding on and initiating correct therapeutic interventions. The constant development of new anesthesia monitoring instruments means that the anesthesiologist will be faced with an overabundance of data about the patient and anesthetic delivery system. The unanswered question is whether the individual anesthesiologist's performance, the human factor, is of far more importance than the implementation of new monitoring equipment or other new safety initiatives in reducing the rate of postoperative complications.

Other factors that have to be considered are that most patients in the studies come from a region where standards of anesthesia and nursing care are good. Almost all the data were collected by a single group of people. This does reduce the possibility of generalizing the results in terms of what might be found in other geographical areas where standards of care and assessment methods may be different. Because detected hypoxic events were treated, we do not really know what the differences in outcome would have been if hypoxic events were neither detected nor treated. The studies were relatively controlled and did not reproduce situations where there was a high likelihood of disaster.

Pulse oximetry monitoring substantially reduced the extent of perioperative hypoxemia, enabled the detection and treatment of hypoxemia and related respiratory events, and promoted several changes in patient care. The implementation of perioperative pulse oximetry monitoring did not significantly reduce the number of postoperative complications, but the question remains whether pulse oximetry improves outcome in other situations. Pulse oximetry has been adopted all over the world in clinical practice and as a tool that guides anesthesiologists in the daily management of patients, in teaching situations, in emergencies, and especially in the care of children. Given the relatively small number of patients studied in these trials and the rare events being sought, the studies of perioperative monitoring with a pulse oximeter were not able to show an improvement in various outcomes.

This review is published as a Cochrane Review in the Cochrane Library (Pedersen T, Pedersen BD, Møller A. Pulse oximetry for perioperative monitoring. In: the Cochrane Library. Issue 3. Oxford: Update Software, 2002) where it will be regularly updated with new data and comments and criticisms on this version.

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