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

Design, Demography, Pulse Oximetry Failure Rate, and Overall Complication Rate

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Background: Although pulse oximetry is currently in widespread use, there are few data documenting improvement in patient outcome as a result of the use of oximetry. The authors describe the study design, patient demographic findings, data validation, pulse oximetry failure rate, and overall postoperative complication rates in the first large prospective randomized multicenter clinical trial on perioperative pulse oximetry monitoring.

Methods: In five Danish hospitals, by random assignment, monitoring did or did not include pulse oximetry for patients 18 yr of age and older, whether scheduled for elective or emergency operations, or for regional or general anesthesia, except during cardiac and neurosurgical procedures. Operational definitions were established for perioperative events and postoperative complications. The data were collected preoperatively, during anesthesia, in the postanesthesia care unit, and until the day of discharge from the hospital or the seventh postoperative day.

Results: Of 20,802 patients, 10,312 were assigned to the oximetry group and 10,490, to the control group. In general, the demographic data, patient factors, and anesthetic agents used were distributed evenly. A slight intergroup difference was found in the distribution of age, duration of surgery, some types of surgery, and some types of anesthesia. The total failure rate of the oximetry was 2.5%, but it increased to 7.2% in patients with American Society of Anesthesiologists physical status 4 (P < 0.00001). In 14.9% of the patients, one or more events occurred in the operating room and 13.5% in the postanesthesia care unit. The overall postoperative complication rate was 9.7%. The total rates of cardiovascular and respiratory complications were 2.78% and 3.50%, respectively. Within the

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postoperative complication and death rates were similar to those in other recent morbidity and mortality studies. In the companion article, we describe the effects of pulse oximetry monitoring on the rate of OR and PACU events and on postoperative complications.14

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