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

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


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 < 0.0001). 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

Received from the Department of Anesthesia, Herlev Hospital, University of Copenhagen, Herlev, Denmark; Esbjerg Central Hospital, Esbjerg, Denmark; Glostrup Hospital, Glostrup, Denmark; Hillerød Central Hospital, Hillerød, Denmark; and Odense Hospital, Odense, Denmark; Massachusetts General Hospital, Boston, Massachusetts; and the Department of Anesthesiology, University of Florida College of Medicine, Gainesville, Florida. Accepted for publication October 29, 1992. Presented in part at the annual meeting of the American Society of Anesthesiologists, San Francisco, California, October 26–30, 1991. Supported by grants from the Gangsted Foundation, King Christian Xth Foundation, Skt. Lukas Stiftelsen’s Foundation, The Research Foundation for Ringkøbing, Ribe og Sønderjylland Counties, S&K Foundation, The Danish Society of Anesthesiology Foundation, Lilly Bethune Lund Foundation, Lundbeck Foundation, Jacob and Olga Madsen Foundation, Svend and Ina Hansen’s Foundation, the Danish Medical Research Counsel, and the Anesthesia Patient Safety Foundation.

Address reprint requests to Dr. Møller: Department of Anesthesia, Rigshospitalet, University of Copenhagen, DK-2100 Copenhagen, Denmark.

Anesthesiology, V 78, No 3, Mar 1993

* Research Fellow, Herlev Hospital.
† Staff Anesthetist, Glostrup Hospital.
‡ Junior Staff Anesthetist, Hillerød Central Hospital.
§ Senior Staff Anesthetist, Esbjerg Central Hospital.
∥ Senior Staff Anesthetist, Glostrup Hospital.
# Staff Anesthetist, Odense Hospital.
¶ Junior Staff Anesthetist, Herlev Hospital.
** Associate Professor and Director Anesthesia Technology, Massachusetts General Hospital.
†† Graduate Research Professor, University of Florida.
‡‡ Chairman, Glostrup Hospital.
§§ Chairman, Hillerød Central Hospital.
∥∥ Chairman, Esbjerg Central Hospital.
## Professor and Chairman, Odense Hospital.
¶¶ Professor and Chairman, Herlev Hospital.
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

The authors thank the numerous anesthesiologists and OR and PACU nurses at each of the participating hospitals who were actively involved in this study. They were essential to the successful completion of this study. They also thank Ms. Marianne Dragsted and Ms. Nina Meier for accurate and careful entering of data and secretarial assistance; Michael Davidsen, M.Sc., and Erik Henriksen, industrial engineer (Department of Medical Statistics) for statistical assistance; the Danish Hospital Institute represented by Torben Jørgensen, medical engineer, and Bent Danneskiold-Samsøe, M.Sc., for invaluable advice and support; and Nellcor, Inc. (Hayward, CA), Ohmeda Co. (Louisville, CO), and Radiometer Co. (Copenhagen, Denmark) for providing the pulse oximeters used in the study.

References


Anesthesiology, V 78, No 3, Mar 1993