Title: VALUE OF CONTINUOUS MONITORING OF MIXED VENOUS BLOOD OXYGEN SATURATION IN THE MANAGEMENT OF CRITICALLY ILL PATIENTS

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Introduction. The oxygen saturation of hemoglobin in mixed venous blood (S$_{O_2}$) is an indicator of the oxygen content in that milieu. Normally, S$_{O_2}$ is assumed to be in the range of 60 to 80%. Continuous measurement of S$_{O_2}$ using a triple lumen flow-directed pulmonary artery catheter with fiberoptic filaments was described by Oximetrix Co. (Oximetrix Inc., Mountain View, CA). The signal is digitally displayed on the monitor as well as continually recorded on paper. Some claims have been made concerning the value of continuous monitoring of S$_{O_2}$ in the management of critically ill patients in ICUs and in the operating rooms. The purpose of this study was to identify whether the availability of S$_{O_2}$ as a continuously monitored signal could have altered patient management decisions made by the medical staff on the basis of clinical and laboratory data and signals currently used in ICUs.

Methods and Materials. Subjects used for this study were critically ill patients requiring arterial cannulation and insertion of a pulmonary artery catheter as part of their medical management in the ICU. The study was evaluated and approved by the Institutional Review Committee on human research. An Oximetrix pulmonary artery catheter was used. The central processor of the device was placed in a specially constructed wooden box in such a way as to cover the digital display of the signal. A lock placed on the box prevented the medical and nursing personnel in the ICU from opening the box. The folded paper used to continually record the signal for a maximum of 72 hours was also not available to the personnel managing the patient. Once the central processor was calibrated and the catheter which was already in place attached, the starting time of the continuous monitoring of the S$_{O_2}$ signal was recorded and the box locked. The key to the lock was carried by one of the investigators. Apart from the continuous recording of S$_{O_2}$, individual detailed studies of patient's status were repeatedly performed. In each study, the physician involved in the care of the patient entered all the clinical data and the results of investigative and laboratory procedures obtained at the time of the study onto a special form. An assessment of the patient's status was entered and the management plan approved by the ICU staff on-call was identified on the form. Each study was considered as a separate decision making. Once the continuously recorded signal was removed from the device at the end of the study, the S$_{O_2}$ recorded at each study time was entered on the form and the significance of S$_{O_2}$ was assessed by the investigators to identify whether it would have caused the physicians managing the patients to make a different decision had they known what the S$_{O_2}$ was. The recorded signal was also carefully scrutinized. Any fall below 60% or increase above 80% lasting longer than 10 minutes were identified. Changes of more than 15% in S$_{O_2}$ lasting more than 10 minutes were also identified. Correlation with the nurses' and physicians' notes at the time these changes took place was made to define whether or not these changes in S$_{O_2}$ could be reconciled with what the nurses' and physicians' notes indicated.

Results. The speed of the motor driving the paper recorder was checked and found to result in an error of 30 seconds in 4 hours. Fifteen patients were studied. There were 10 males and 5 females. Their ages ranged from 42 to 75 years. Nine patients died in the ICU and 6 were discharged from the hospital. The S$_{O_2}$ signal was continuously recorded on paper for a total of 1,055 hours and 11 minutes in all 15 patients combined. Fifty-six hours and 25 minutes or 6% of the total recordings were disallowed because of dry pens, power disconnect or inadequate light intensity. There was a total of 176 individual studies. Only 3 studies were excluded because S$_{O_2}$ signals at the time studies were made were not accurate. In 141 studies (81.5%) S$_{O_2}$ values were compatible with the decisions made on the basis of standard studies that included some or all of the following: blood pressure, pulmonary artery pressure, pulmonary capillary wedge pressure, CVP, heart rate, cardiac output, pulmonary shunt fraction (Qp/Qs), SMA-17, CBC, serum osmolality, colloid osmotic pressure, PT and PTT, PaCO$_2$, PaO$_2$, pH, tidal volume, respiratory rate, ventilator settings, fluid intake and output for 2 hours prior to the study, and chest x-rays. In 32 studies (18.5%), the S$_{O_2}$ signal was incorrectly too high (90.6%) or too low (9.4%). None of the studies revealed an S$_{O_2}$ value that was not compatible with the findings yet would have been the correct signal to base the management decision on. Close survey of all tracings revealed no incidence of changes in S$_{O_2}$ that were not compatible with standard findings in studies performed before or after the occurrence or with data obtained from nurses' and physicians' notes between studies.

Discussion and Conclusion. The S$_{O_2}$ signal as measured by the Oximetrix device was compatible with findings obtained by standard measurements used in the ICU in a majority of cases. However, we believe that in this study awareness of S$_{O_2}$ value by the medical team managing the patient would not have resulted in a different or better line of management than was based on standard findings.

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