Oxygen is both a blessing and a curse in the intensive care nursery. It is lifesaving in many situations, yet oxygen toxicity is thought to be a factor in bronchopulmonary dysplasia and retinopathy of prematurity, and a rapid response to changes in oxygenation is crucial in many other disease states. Thus, the need to control oxygen with precision is a feature of modern neonatology. On the other hand, the lability of cardiopulmonary function in the newborn makes it impossible to achieve stable oxygenation in many babies and requires monitoring and adjustment to be ongoing. Even with these measures, it is unrealistic to expect close control of blood oxygen, and values will stray outside the intended range in many sick neonates.

Repeated measurement of arterial blood has been a mainstay of nursery management but has the drawbacks of being invasive, of being only intermittent, and, ultimately, of requiring transfusion for blood replacement in the tiny premature infant. Since the advent of transcutaneous oxygen (tcPO₂) electrodes, the hope of continuous surveillance of arterial oxygen without repeated blood drawing has led to the rapid proliferation and widespread use of these devices. In the hands of the original investigators, tcPO₂ electrodes have proved to be both accurate and clinically valuable. However, the technique is not easy and the electrodes require exacting engineering to perform as intended. As a result of both variable manufacturing techniques and misapplication by clinicians in the field, it appears that erroneous clinical judgments are being made on the basis of tcPO₂ measurements.

In an effort to assess this situation and develop conclusions and recommendations, an expert committee was convened Dec 5 and 6, 1986, by the American Academy of Pediatrics, with cosponsorship of the FDA through an enabling grant. This report represents the thinking of that committee.

HISTORY

Huch et al\(^1,2\) demonstrated excellent correlation of tcPO₂ values with PaO₂ values through a wide range of arterial oxygen tensions in the newborn. This finding was replicated by other investigators using the Huch electrode.\(^3,4\) Versmold et al\(^5\) reported good correlation with other electrodes. Duc et al\(^6\) reported a striking difference in accuracy using two electrodes of different design simultaneously in the same infant.

Following these initial results demonstrating excellent correlation, investigators became interested in determining the conditions in which the electrode might be expected to be inaccurate. Peabody et al\(^7\) found that in babies with severe hypotension and during tolazoline infusion tcPO₂ values did not correlate well with those of PaO₂. Versmold et al\(^8\) found that the tcPO₂ result was inaccurate only in the most severely ill infants, with severe hypotension and diminished peripheral perfusion. Several investigators\(^9,10\) also commented on the inadequacy of tcPO₂ monitoring in infants with bronchopulmonary dysplasia.

More recently, concern has arisen regarding the accuracy of tcPO₂ monitoring in infants with hyperoxemia. In fact, as early as 1974, Fenner et al\(^11\) demonstrated poor correlation of the Huch electrode in the hyperoxemic range, particularly in sick infants. Using the Hellige electrode in 26 infants, Duc et al\(^12\) found that 16% of the cases of hyperoxemia (PaO₂ > 100 mm Hg) were missed. Subsequently, Martin et al\(^13\) studied the Radiometer TCM2 in 68 neonates and found that 22% of the cases of hyperoxemia were missed, with a mean difference of 17 mm Hg in the hyperoxemic range.
Palmisano and Severinghaus studied the Radiometer combined electrode in both adults and infants and found a significant underestimation of PaO₂ in the hyperoxemic range. Other investigators have further supported this finding. Heightened impact of poor arterialization, due to the shape of the oxyhemoglobin dissociation curve, has been postulated to explain this finding.

In summary, it is possible to assess PaO₂ through tcPO₂ monitoring throughout a wide range of PaO₂ values. However, several investigators have found that, in infants with hyperoxemia (>100 mm Hg), the tcPO₂ sensor significantly underestimates the PaO₂.

**TECHNIQUE**

The tcPO₂ electrode measures the partial pressure of oxygen at the skin surface. It consists of a platinum cathode and a silver reference anode encased in an electrolyte solution and separated from the skin by an oxygen-permeable membrane. A heating coil within the sensor causes local hyperemia and "arterializes" the blood within the capillaries beneath the electrode. Oxygen diffuses through the capillaries and skin and then through the membrane where it is reduced at the cathode. An electric current is generated proportional to the PO₂ and is displayed by the monitor, usually converted to millimeters of mercury.

The skin surface PO₂ will approximate the PaO₂ through a balancing out of several factors. Heating by the electrode causes a rightward shift of the oxyhemoglobin dissociation curve which increases oxygen release. Heating also causes decreased solubility of oxygen in the blood which further increases PO₂. These factors are counterbalanced by others that decrease the skin surface PO₂. Heating causes increased tissue consumption of oxygen. Oxygen consumption by the electrode and the diffusion gradients of the skin and the membrane also lower measured PO₂.

Thus, the tcPO₂ electrode is an extremely critical instrument whose performance depends upon the interrelatation of many factors. Subtle differences in the temperature of the sensor, membrane properties, or the makeup of the electrode itself can affect the measured PO₂. In addition, conditions of the patient may alter this measurement: among these are skin perfusion, pharmacologic agents that affect the microcirculation, hypothermia, edema, and skin thickness.

**ELECTRODE PERFORMANCE CRITERIA**

The electrode-skin system is a functional unity. Electrode construction and performance must not overlook the rather limited oxygen availability from neonatal skin, even after maximal hyperemia has been reached. In vivo performance is most important; however, correct in vitro performance is a necessary prerequisite for proper in vivo function.

**In Vitro**

1. Linearity: This is achieved by calibration with nitrogen and air; deviation from the true slope should be less than 3%.
2. Zero calibration reading should differ less than 4% from the current in air, ie, <6 mm Hg.
3. Temperature: This should not deviate by more than 0.6°C for more than 20 seconds within any 1/4-hour.
4. Overheating: If the electrode core temperature increases to >46°C, the device should automatically turn off within a few seconds.
5. Response time: Time for 90% response should be <20 seconds. Data averaging time should be <11 seconds.
6. Drift should be <5% during the calibration period. The manufacturer must indicate the duration of the calibration period in which this drift should not be surpassed. In practice, this calibration period should not be less than four hours.
7. Reproducibility, O₂ consumption, must be such that, during a particular testing period on any one individual with stable skin perfusion, the relation between tcPO₂ and PaO₂ values in infants with normoxemia and hyperoxemia remains constant.

Heat conductivity is important. It determines the resulting temperature on the skin and is itself determined by several factors: membrane material, electrolyte layer, electrode housing, insulation, location of heating elements and heat control, etc, all determining performance in vivo.

**In Vivo**

tcPO₂ should reflect arterial PO₂ levels and changes with an accuracy of ±15% in the entire intended operating range. This should be established in a normal infant population, and in vivo performance should be checked against a standard reference (arterial PaO₂ from a comparable sampling site). Information concerning the model and precision of the blood gas analyzer should be given.

**CLINICAL SETTING**

TcPO₂ monitoring has become a routine part of neonatal intensive care. Because of its continuous readout, it provides an adjunct to intermittent PaO₂ measurements in the detection of both hypo- and hyperoxygenation. In infants suffering from respi-
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ratory or cardiac disorders, it provides a continuous assessment of the effects of treatment changes such as ventilator settings or inspired oxygen concentrations. Transient fluctuations in PO2 values can be ascertained in infants with inconsistent respiratory effort or premature infants with severe recurrent apneic episodes. Inaccurate assessment of PaO2 with this technique most often occurs in infants with poor skin blood flow due to shock, hypothermia, hydrops, etc. It is also helpful in unstable infants, extremely low birth weight infants, and those with persistent fetal circulation. Comparison with an arterial blood sample for PaO2 measurement should be done each time the electrode is applied. The use of electrodes simultaneously placed over the skin supplied by pre- and postductal blood may provide information regarding right-to-left shunting of blood through a patent ductus arteriosus.

Monitoring is appropriate within certain clinical settings including (1) neonatal intensive care units, (2) operative and postoperative neonatal surgical facilities, (3) intermediate or Level II nurseries for ongoing care of infants with cardiorespiratory disorders or for the assessment of newborn infants who are unstable, and (4) during transport of unstable infants. Its use may be appropriate in some Level I nurseries where it is the policy to observe infants with mild respiratory distress or who cannot be transferred immediately to a Level II or III unit because of distance or delays in transport. It is not recommended for occasional use in a Level I nursery because infrequent or irregular use would not permit hospital personnel to maintain the necessary skills. Appropriate personnel (laboratory medicine technicians, respiratory therapists, nurses, or physicians) trained in the application and interpretation of tcPO2 monitoring, and for drawing arterial blood for correlation, must be available at all hours to assure correct use. These personnel should provide quality control, including calibration of the electrode, membrane inspection and replacement, testing of the electrode thermistor, and maintenance of performance records. The user should be familiar with all sources of equipment or user error, and the institution should provide preventive maintenance on a regular basis through a medical instrument facility.

LABELING RECOMMENDATIONS

The committee believes that additional labeling information should accompany each tcPO2 monitor, to inform the user of both performance characteristics and limitations of their system. Thus, in addition to a basic manual of operations for mem-braning, calibrating, measuring, recording, and maintaining the equipment, the following data should be provided.

Performance Data

These should take the form of tcPO2 v PaO2 correlations at the recommended electrode temperature and obtained with the same system that is being marketed. These data should be systematically collected from a minimum of 25 human neonates <1 month of age who are preponderantly preterm and ideally of very low birth weight (≤1.5 kg). The data should be presented in graphic form, plotting tcPO2 against PaO2 as the independent variable. The slope, intercept, coefficient of linear correlation, and standard error of the estimate should be calculated from the data. The regression line should be drawn through the data points. If comparable accuracy cannot be demonstrated during hyperoxemia (up to 150 mm Hg) this limitation should be stated. Information indicating the source of these data should be provided.

Limitations

The following specific limitations of tcPO2 monitoring should be indicated.

1. TcPO2 may underestimate PaO2 in the infant with hyperoxemia.
2. Inappropriate electrode temperature may adversely influence its performance.
3. Compromised hemodynamic status or excessive pressure on the electrode may cause tcPO2 to underestimate PaO2.
4. Performance may be suboptimal if the electrode is sited over poorly perfused areas such as pressure points, bony prominences, or distal extremities.
5. TcPO2 may underestimate PaO2 beyond the neonatal period, especially in infants with chronic lung disease.
6. Use of the heated electrode may cause the skin to blister, especially in very low birth weight infants or if perfusion is impaired.
7. It cannot be used to estimate PO2 without periodically correlating with arterial blood gas samples.

The manufacturer should indicate other potential limitations that relate to their specific device.

EDUCATION

TcPO2 monitoring is a deceptively simple technique. The expectation of many clinicians is that all that need be done is place an electrode on the
skin surface and, presto, we have a substitute for arterial blood gas sampling. Unfortunately, the procedure is not so simple.

TcPO₂ monitors are more equivalent to laboratory instrumentation than ECG and respiration monitors. The most well-designed tcPO₂ device will perform to standard only if it is well maintained, properly calibrated, and appropriately placed on a patient whose physiologic state will allow accurate reflection of arterial blood gases through skin surface measurement. Even if all of these conditions are met, interpretation of results requires a thorough understanding of some rather complex biophysical, physiologic, and biochemical principles. Therefore, physicians, nurses, respiratory therapists, and anyone else who may be charged with using the device and interpreting the information must receive concentrated and continuing education on two fronts.

First, interpretation of results obtained from any transcutaneous device requires a thorough understanding of the physiologic principles underlying the technique. Second, and equally important, users must be trained in the technical aspects of the particular device in use in their institution, including quality control, application, maintenance, accuracy, response characteristics, and limitations.

Use of tcPO₂ monitors without an accompanying continuing education and quality assurance program will almost assuredly result in failure of the device to perform to standard and may well prove detrimental to the care of the critically ill newborn.

SUMMARY

Errors in measurement of tcPO₂ that misrepresent arterial values are dangerous because they may lead to exposure of the premature to inappropriately high oxygen levels. This is particularly so because, in the field, tcPO₂ values are frequently used as estimates of Pao₂ values and not merely for oxygen trending. The tcPO₂ electrode is such that underestimation of Pao₂ is particularly likely at high Pao₂ values (>100 mm Hg) with minor errors in technique or minor variations in electrode design. Recent evidence suggests that small details in design may have rendered some of the current commercial tcPO₂ electrodes inaccurate in the hypoxic range, with consequent risk to premature infants for eye or lung damage. Good performance of a tcPO₂ electrode requires certain benchmark standards that are described in this report. Users must thoroughly understand the underlying physiology and the required technique. Limitations of the technique are not widely understood and marketing, in some instances, appears to be misleading regarding the simplicity of the method. Each manufacturer needs to present performance data obtained on the skins of human neonates, throughout the range of Pao₂ values for which use is recommended, using the device that is being marketed and specifying crucial details such as operating temperature. Despite these limitations, the Task Force believes that this technique, when a quality electrode is used, and performed with care and understanding, is a valuable tool in newborn intensive care.

Task Force Members
Gordon B. Avery, MD, PhD, Chairman
Eduardo H. Bancalari, MD
Arthur Engler, RN
Timothy D. Guilfoile, RT
Ann Johnston Hodgson, MD
W. Alan Hodson, MD
Albert Huch, MD
Renate Huch, MD
Alfred W. L. Jay, PhD
Jerold F. Lucey, MD
Richard J. Martin, MD
FDA Liaison
Claudia Gaffey, MD
AAP Staff
Jean D. Lockhart, MD

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