A Pilot Study of Neonatal and Pediatric Esophageal Pulse Oximetry

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BACKGROUND: In this pilot study we explored the suitability of the esophagus as a new measuring site for blood oxygen saturation (\(\text{SpO}_2\)) in neonates.

METHODS: A new miniaturized esophageal pulse oximeter has been developed. Five patients (one child and four neonates) were studied.

RESULTS: \(\text{SpO}_2\) values were obtained in the esophagus of all patients. A Bland and Altman plot of the difference between \(\text{SpO}_2\) values from the esophageal pulse oximeter and a commercial toe pulse oximeter against their mean showed that the bias and the limits of agreement between the two pulse oximeters were +0.3\% and +1.7\% to −1.0\%, respectively.

CONCLUSIONS: This study suggests that the esophagus can be used as an alternative site for monitoring blood oxygen saturation in children and neonates.

Pulse oximetry, invented in 1975, has been one of the most significant technological advances in clinical monitoring.\(^1\)\(^–\)\(^4\) Although generally reliable, pulse oximeters do fail, especially in patients undergoing prolonged procedures, such as cardiac, vascular, reconstructive or neurosurgery, at just the time when the measurement of blood oxygen saturation (\(\text{SpO}_2\)) would be most important.\(^5\) There have been numerous studies of the accuracy of pulse oximeters in adults,\(^1\)\(^–\)\(^10\) neonates, and pediatric patients.\(^11\)\(^–\)\(^20\) Several of these studies have detailed the limitations of the reliability of conventional pulse oximetry when measuring in the latter two groups. In order to see if some of these limitations can be avoided, the present study aimed at exploring the feasibility of esophageal (ES) reflectance pulse oximetry in pediatric patients and neonates. Previous studies have shown that measurable photoplethysmographic (PPG) signals can be detected in the esophagus of healthy adult patients during anesthesia and also adult patients undergoing cardiothoracic surgery.\(^21\)\(^–\)\(^23\) A novel neonatal ES pulse oximeter is described and preliminary results from a clinical investigation are presented.

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However, temperature safety tests both in vitro and in vivo, were conducted to confirm that temperature increases in the esophagus at the outside wall of the nasogastric tube adjacent to the probe would not be of clinical significance. The methodology was the same as that used in a previous study for an adult ES pulse oximetry probe.24

**Patients and Measurements**

Local research ethics committee approval was obtained for this proof-of-concept pilot study and written informed consent was obtained from all parents. Five neonates (three male, two female) were studied on the neonatal and pediatric intensive care units. The age range (days, ± sd) was (5 to 1398, ± 606) and the weight range (kg, ± sd) was (1.9–10.0, ± 3.3). The ES SpO₂ probe was advanced gently through the mouth to a maximum depth of 15 cm from the lips. The babies were all mechanically ventilated and adequately sedated. The probe was withdrawn slowly, and PPG signals were observed at various depths to determine the optimal measuring site at which reliable signals with high signal-to-noise ratio were obtained. The probe was then left (taped to the cheek of the...
patient) at this depth for the duration of the study for approximately 10 min and PPG traces and derived $\text{SpO}_2$ values were recorded simultaneously. During the ES measurements, values of blood oxygen saturation from a commercial toe (CT) pulse oximeter (Datex Ohmeda Biox 3740 Pulse oximeter (GE Healthcare) with software version 15 with disposable Datex Ohmeda toe sensor (Oxytip Allfit sensor, OXY-AF)) were also recorded for comparison.

Data Analysis and Statistics

The limits of agreement between the ES $\text{SpO}_2$ results and those from the CT pulse oximeter were calculated using the between-method differences analysis outlined by Bland and Altman.\textsuperscript{25}

RESULTS

Results from the Thermal Safety Tests

The increase in temperature at the outside surface of the ES tube in the \textit{in vitro} tests was no more than 0.1°C for both the red and infrared emitters. In the \textit{in vivo} tests the increase in temperature at the outside surface of the ES tube was <0.5°C for the red emitter and 0.4°C for the infrared emitter.

Results from the Investigation of Esophageal PPG Signals

Good quality PPG signals from the esophagus were recorded in all patients. The measured effective signal-to-noise ratio was always better than 40 dB at the output of the system. Figure 3 depicts typical PPG traces from the esophagus of a 3.2 kg, 5-day-old neonate. The low frequency (5 s period) variations on both traces are an artifact due to the mechanical ventilator.

Comparisons of $\text{SpO}_2$ Measurements from the Esophageal (ES) and Commercial toe (CT) Pulse Oximeters

Eighteen pairs of $\text{SpO}_2$ values from the five patients were used to compare the ES and the CT pulse oximeters. Figure 4 is a plot of the difference between the ES and the CT $\text{SpO}_2$ values against their mean. As no obvious relation between the difference and the mean is revealed in Figure 4, calculations of the bias, estimated by the mean difference ($d$), and the standard deviation of the differences ($s$) were performed to assess the degree of agreement between the two methods. The bias ($d$) is the ES pulse oximeter reading minus the CT pulse oximeter reading (ES–CT) and was $+0.34\%$ with a standard deviation ($s$) of $0.67\%$. Hence, the limits of agreement for the $\text{SpO}_2$ data (ES and CT) were:

\[d - 2s = +0.34 - (2*0.67) = -1.00\%\]
\[d + 2s = +0.34 + (2*0.67) = +1.70\%\]

DISCUSSION

A new miniaturized reflectance pulse oximeter has been developed to measure $\text{SpO}_2$ within the esophagus of neonates and children. The very small temperature increases recorded in the safety measurements on the probe confirm that there is negligible risk of thermal injury to the esophagus. The recorded ES PPG signals from all patients were of high quality and in a direct comparison between the ES pulse oximeter and a CT pulse oximeter, using Bland and Altman analysis, the preliminary $\text{SpO}_2$ results from the two instruments were in good agreement. This pilot study supports the initial hypothesis that the esophagus may be used as an alternative measuring site for $\text{SpO}_2$ in neonates and children. This is the first report of the calculation of $\text{SpO}_2$ values from PPG signals recorded in the neonatal esophagus.

The next step in developing this system into a clinically useful monitor will be to study a larger population of neonates when ES $\text{SpO}_2$ values will be compared with those from commercial pulse oximeters and a “gold standard” CO-oximeter. A further study comparing ES with peripheral pulse oximetry in a group of neonates whose peripheral perfusion is compromised will be necessary to test the hypothesis.
that ES pulse oximetry is still feasible in neonates at times when peripheral pulse oximetry probes fail. This has already been demonstrated in adults and if it were to prove true in neonates, it would greatly enhance the clinical potential of ES pulse oximetry.

REFERENCES