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 (Spo_2) in neonates.
METHODS: A new miniaturized esophageal pulse oximeter has been developed. Five patients (one child and four neonates) were studied.
RESULTS: Spo_2 values were obtained in the esophagus of all patients. A Bland and Altman plot of the difference between 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 (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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METHODS

Instrumentation

Esophageal PPG/Spo_2 Probe Design

A miniaturized reflectance ES pulse oximeter probe was constructed in our laboratory (dimensions: 14 mm × 2 mm), comprising one infrared (880 nm) and one red (655 nm) surface mount emitter and a surface mount photodetector (Fig. 1). The ES probe was designed to be small enough to slide down the lumen of a plastic transparent disposable size 12 French (external diameter of 3.8 mm) nasogastric tube.

Processing System

A battery-powered processing system was also developed in our laboratory to pre-process, record, and display ES PPG signals and estimate Spo_2 values on a laptop computer. A block diagram of the processing system is shown in Figure 2; it is similar to that used for adults.[21] The detected signal was separated into two channels (red and infrared) by a demultiplexer. After passing through the isolation barrier the AC and DC components of the infrared and red PPG signals were extracted using filters to give four separate outputs (Fig. 2). These four PPG output signals were digitized by a 16-bit data acquisition card (DAQCard-AI-16XE-50, National Instruments Corporation, Austin, TX) in the laptop computer and analyzed by a *Virtual Instrument (VI*) implemented in *LabView* (National Instruments Corporation, Austin, TX). The ES PPG data were recorded and displayed in real-time by the *VI* on the computer screen. The *VI* also displayed an online estimation of ES Spo_2 (Fig. 3).

Thermal Safety Tests

The two emitters are thermally insulated from the tissue by the plastic wall of the nasogastric tube and the operating current of the emitters is relatively low.

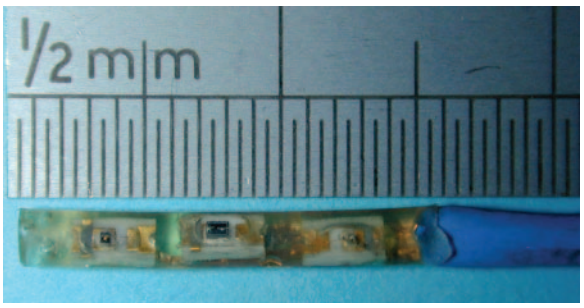

Figure 1. Photograph of the probe, the surface-mount photodetector is in the center, the infrared LED emitter is on the right and the red LED is on the left.

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 Spo_2 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

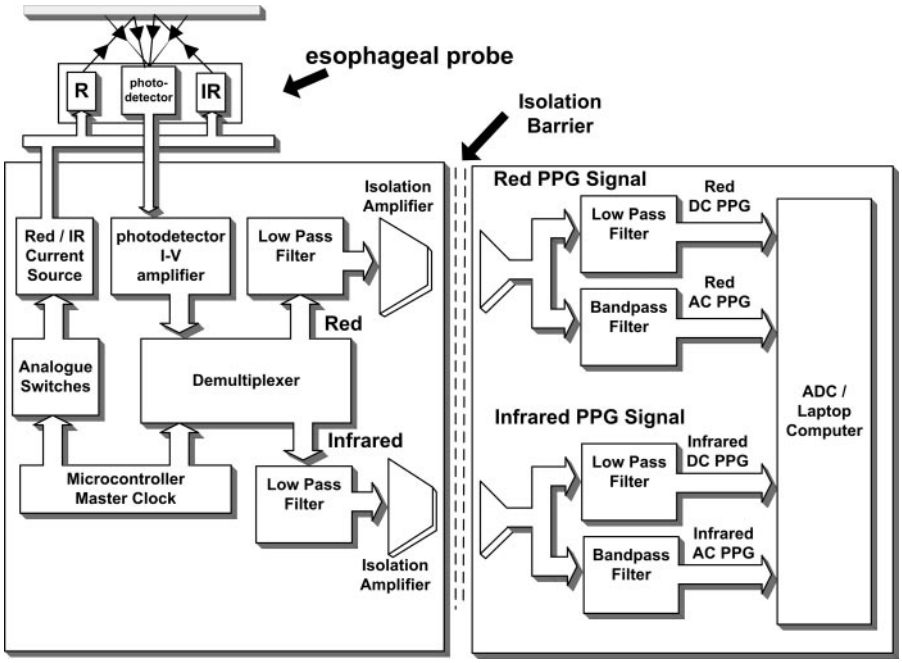

Figure 2. Esophageal pulse oximetry processing system.

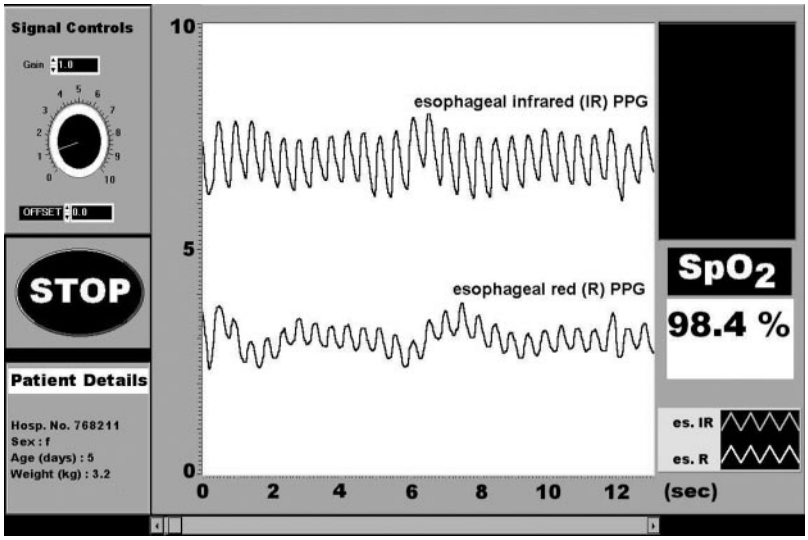

Figure 3. Typical photoplethysmographic traces obtained from a neonatal human esophagus at two wavelengths, infrared (top trace) and red (bottom trace).

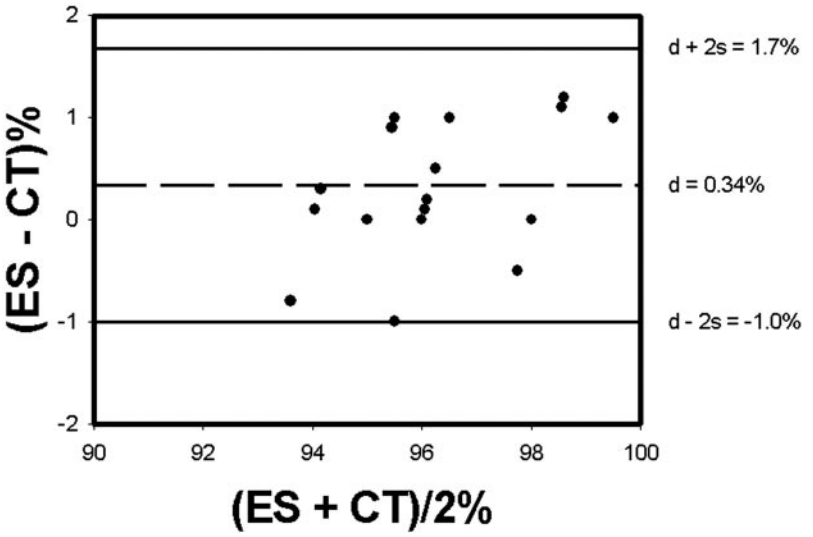

Figure 4. Comparisons of Spo_2 values from the esophageal (ES) and commercial toe (CT) pulse oximeter. The difference of ES Spo_2 minus CT Spo_2 (ES–CT) is plotted against their mean value. (d: mean difference; s: standard deviation).

patient) at this depth for the duration of the study for approximately 10 min and PPG traces and derived 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 Spo_2 results and those from the CT pulse oximeter were calculated using the between-method differences analysis outlined by Bland and Altman.[25]

RESULTS

Results from the Thermal Safety Tests

The increase in temperature at the outside surface of the ES tube in the *in vitro* tests was no more than 0.1°C for both the red and infrared emitters. In the *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 Spo_2 Measurements from the Esophageal (ES) and Commercial toe (CT) Pulse Oximeters

Eighteen pairs of 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 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 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 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 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 Spo_2 in neonates and children. This is the first report of the calculation of 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 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[21] and if it were to prove true in neonates, it would greatly enhance the clinical potential of ES pulse oximetry.

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