Summary of the results for the clinical study “Improving respiratory monitoring by directly capturing the electrical activity of the diaphragm”

Introduction

In preterm infants, respiration is currently measured using chest impedance (CI). Whilst proven to be a useful method, CI has important limitations, such as inaccuracies in monitoring respiration due to cardiac interference and nonbreathing-related chest wall movement. Respiration can also be determined by directly measuring the electrical activity (electromyography) of the diaphragm (dEMG). Bambi Belt B.V., a Dutch med-tech company, aims to market a product that measures dEMG in neonates specifically. To assess the functioning of this new device and improve the algorithm used in this device, neonatal reference data including dEMG data has to be obtained with a CE-certified device, such as the Delsys Trigno Wireless Biofeedback System.

Methods

Observational within-subject explorative study in which 35 measurements including dEMG are obtained in neonates admitted to the neonatology department in the Jeroen Bosch Hospital (JBZ), the Netherlands. These measurements are obtained with a marketed dEMG recording product (Delsys Trigno Wireless Biofeedback System (Delsys Inc., Natick, USA) for a period of 1-3 hours. They are additional to routine monitoring, including heart rate, ECG and CI measuring.

Results

In total, 64 hours and 0 min of data were collected in 35 measurements, performed in 32 different neonates. 16 participants were male (17 measurements), 16 were female (18 measurements). Mean gestational age of was 30 weeks + 3 days, with a mean birth weight of 1425 g. Mean age at the time of the measurement was 35 weeks + 2 days, with a mean weight of 2082 g. Six measurements were performed in infants on minor respiratory support (high flow / low flow supplementary oxygen), in all other measurements, infants did not receive any kind of respiratory support.

No adverse events were reported during the study.

Compared to reference data (i.e. data obtained in infants via routine monitoring using a Philips monitor), the performance of Bambi Belt B.V. algorithm to retrieve heart rate, ECG and respiratory information from raw dEMG data was assessed with Bland-Altman testing. Fragments of data where discrepancies between reference data and Bambi Belt results were above average were manually (i.e. visually) zoomed in on to improve the algorithm. This was typically done by creating debug plots in order to visualise the behaviour of internal components of the algorithm (e.g. threshold levels) and identifying potential changes to these components. The performance of revised algorithms was then again tested using Bland-Altman testing. Several such iteration cycles were performed.

In parallel, the Bambi Belt itself (so not the Delsys system) was used in a “first in man testing” clinical study mounted in the Amsterdam Medical Center in the Netherlands. In that study, dEMG data was obtained using the Bambi Belt Solution in addition to routine monitoring, in neonates admitted to a neonatal intensive care unit.

Measurements in the JBZ with the Delsys device were then used alongside these Amsterdam-Belt measurements to identify if discrepancies between reference data versus dEMG data originated from algorithmic issues or from hardware issues. This could be done because, in the case of algorithm issues, discrepancies would remain visible when running the algorithm in Amsterdam data as well as

in JBZ data, whereas hardware issues would not be confirmed in the JBZ data (obtained with the CE-certified Delsys device instead of with the Bambi Belt Solution).

Additionally, the final 6 JBZ measurements were used to investigate if a challenge occurring in the Amsterdam study (intra-costal retractions of neonates resulting in suboptimal electrode-to-skin-contact) could be overcome by different placement of electrodes. In the specific scenario of intra-costal retractions, skin-electrode contact mainly reduces in the medial chest area. In the JBZ measurements, it was therefore assessed if more lateral placement of electrodes, on the ribs, a more rigid part of the chest, yielded results comparable to the medial measurements.

Conclusion

Overall, the level of agreement between dEMG data and CI data became within pre-defined product acceptance criteria (+8 to -8 bpm for heart rate and +15 to -15 brpm) for respiratory rate with the improved dEMG-algorithm. Therefore, a subsequent clinical study can be set up, to investigate non-inferiority of monitor performance of the Bambi belt using the final algorithm achieved based on this (JBZ) study and the Amsterdam study.