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Cardiorespiratory monitoring based on diaphragm electromyography

Towards wireless and non-adhesive monitoring in newborn infants

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Feasibility of wireless cardiorespiratory monitoring with dry electrodes incorporated in a belt in preterm infants

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Abstract

Objective

Monitoring heart rate (HR) and respiratory rate (RR) is essential in preterm infants and is currently measured with ECG and chest impedance (CI), respectively. However, in current clinical practice these techniques use wired adhesive electrodes which can cause skin damage and hinder parent-infant interaction. Moreover, CI is not always reliable. We assessed the feasibility of a wireless dry electrode belt to measure HR and RR via transcutaneous diaphragmatic electromyography (dEMG).

Approach

In this prospective, observational study, infants were monitored up to 72 hours with the belt and standard CI. Feasibility of the belt was expressed by its ability to retrieve a respiratory waveform from dEMG, determining the percentage of time with stable respiration data without signal errors ('lead-off' and Bluetooth Loss Error ('BLE')), skin-friendliness of the belt (skin score) and by exploring the ability to monitor trends in HR and RR with the belt.

Main results

In all 19 included infants (median gestational age 27.3 weeks) a respiratory waveform could be obtained. The amount of signal errors was low (lead-off 0.5% (IQR 0.1-1.6) and BLE 0.3% (IQR 0.1-0.9)) and 76.5% (IQR 69.3-80.0) of the respiration measurement was stable. No adverse skin effects were observed (median skin score of 3 (3-4)). A similar HR and RR trend between the belt and CI was observed.

Significance

Dry electrodes incorporated in a non-adhesive belt can measure dEMG in preterm infants. The belt provided a HR and RR trend similar to CI. Future studies are required to investigate the non-inferiority of the belt as a cardiorespiratory monitor compared to CI.

Introduction

Preterm and very low birth weight infants often experience intermittent hypoxia and bradycardia due to lung immaturity and impaired control of breathing.[1] When prolonged, these hypoxic events are associated with neurodevelopmental impairment.[2] Therefore, cardiorespiratory monitoring in infants admitted to the neonatal intensive care unit (NICU) is essential to detect these episodes of hypoxemia and to start adequate treatment.[3]

To date, cardiorespiratory monitoring is performed by the ECG and chest impedance (CI). CI detects breathing as changes in electrical impedance between two electrodes on the chest, based on changes in intra-thoracic volume. However, chest wall movements and cardiac interference may impact the impedance signal, making this technology for respiratory monitoring less reliable.[4,5] With transcutaneous electromyography of the diaphragm (dEMG) direct insight in respiration is obtained by measuring the changes in electrical activity of the main respiratory muscle, the diaphragm. Furthermore, from the electrical signal, the ECG can be extracted and in turn the heart rate (HR) can be calculated.[6] Previous studies have shown that dEMG can be used as a cardiorespiratory monitor in the NICU.[7] Furthermore, studies suggest that cardiorespiratory monitoring via dEMG can improve apnea classification [8] and assess the effect of changes in respiratory support or respiratory stimulants (e.g. caffeine) on diaphragm activity.[9-12]

Up to now, CI and dEMG are recorded with adhesive Ag/AgCl electrodes using conductive gel, ensuring proper electrode-skin contact. However, these electrodes can dry the skin and cause skin irritation/damage, especially in extremely preterm infants (gestational age (GA)<28 weeks).[13-15] Another disadvantage of the currently used adhesive electrodes are the attached wires, which hinder nursing care and parent-infant interaction.[16] Therefore, preferably HR and respiratory rate (RR) are measured wirelessly using dry electrodes.

In recent years, different types of wireless wearable non-adhesive sensors (e.g. jacket, t-shirt and belt) have been developed.[17-20] However, covering of the entire chest and abdomen is undesirable or sometimes even impossible in the NICU population. This is probably why these wearables have to date not been implemented in neonatal care. Moreover, as previously explained, it is preferred to measure dEMG instead of CI, as diaphragm activity is a measure for breathing effort. Recently, a novel wireless sensor belt (Bambi Medical B.V., Eindhoven, The Netherlands) was developed for neonatal use, using dry electrodes to measure respiration and HR based on electromyography of the diaphragm. The aim of this study was to determine the feasibility of measuring diaphragm activity in infants admitted to the NICU with this wireless belt with incorporated dry electrodes. Feasibility of the belt was assessed by its ability to retrieve a respiratory waveform from dEMG, the percentage of time with stable respiration data, its ability to monitor trends in HR and RR, and the skin condition after use.

Method

This prospective, observational study was conducted in the NICU of the Emma Children's Hospital, Amsterdam UMC, Amsterdam, The Netherlands between September 2020 and June 2021. Medical ethical approval was obtained from the institutional review board of the Amsterdam UMC, location AMC in The Netherlands (METC AMC, ABR registration, NL72488.018.20). This study was also registered at the Health and Youth Care Inspectorate (VGR2019992, medical device without a CE-mark).

Study population

Infants born with a gestational age (GA) > 26 weeks requiring CI monitoring were eligible for inclusion if they were clinically stable and written parental consent was obtained. Exclusion criteria were thoracic and abdominal congenital anomalies, lesions or treatment interventions that prevented placement of the belt.

Study procedures

The silicone belt has three incorporated dry electrodes at specific distances enabling placement of the two outer electrodes at the costal margin in the nipple line and the middle electrode in line with the sternum. The appropriate belt size to use for the measurement was based on the infant's weight and nipple distance (size 1: <1000 g and ± 3.5 cm, size 2: 1000-2500 g and ± 5.0 cm, size 3: 2500-3500 g and ± 7.0 cm, size 4: >3500 g and ± 9.0 cm). A sensor module attached to the belt wirelessly transmitted the measured dEMG signal via Bluetooth to a receiver module (REM), connected to a bedside computer. Data was recorded using customized software (Polybench, Applied Biosignals, Weener, Germany). The electrical activity of the diaphragm was measured with a sampling frequency of 1 kHz. The performance of the belt was continuously assessed by recording the input impedance providing information on electrode-skin contact (inadequate contact defined as an increase in measured impedance was marked as 'lead-off') and by the state of wireless connection (inadequate connection defined as the REM not receiving data within a period of 100 milliseconds was marked as Bluetooth Loss Error (BLE)), both measured at a sampling frequency of 500 Hz.

Routine CI monitoring was continued throughout the study. Numerical HR and RR data were extracted from the patient monitor (Intellivue MP90, Philips Healthcare, Eindhoven, The Netherlands) and imported in the bedside computer. The measurement setup is visualized in Figure 1.

Routine care was continued during the measurements. Annotations were made at the start and end of care procedures (e.g. feeding, kangaroo care, medical interventions, changes in position, movement and removal of the belt) to explain signal artefacts afterwards. The measurement lasted for a maximum of 72 hours to capture daily clinical practice.

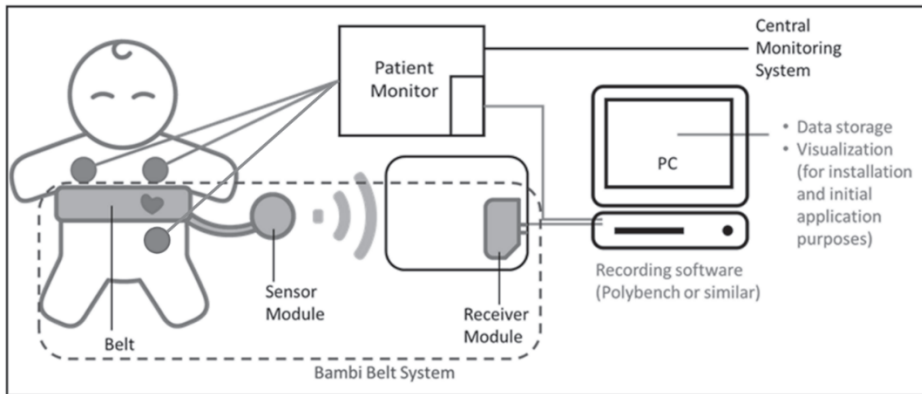


Figure 1 - The measurement setup. The adhesive electrodes used for standard cardiorespiratory monitoring were attached at the original location, visualised by the three grey dots. The diaphragm activity measured with the belt was wirelessly transmitted with the sensor module to the receiver module. This data and the numerical heart rate and respiratory rate data measured with the patient monitor were transported to a personal bedside computer to synchronise and record these signals.

Study outcomes

To describe the study population, the following baseline characteristics were collected: GA, birth weight, age and weight at inclusion, sex, nipple distance, Apgar scores, medication affecting breathing and respiratory support modality.

Feasibility of the belt was assessed in several ways. First, we assessed the following signal parameters: 1) the time a drift was observed in the raw dEMG signal after placing the belt [21], 2) the ability to obtain a proper respiratory waveform from the raw dEMG signal, 3) the percentage of time with signal errors (%lead-off and %BLE), 4) the percentage of time respiration was measured without artefacts, lead-off and BLE (%stable data), calculated for the total measurement and for the time the infants was subjected to kangaroo care and clinical handling. Second, the effect of belt placement on skin integrity was quantified with the Neonatal Skin Condition Score (NSCS).[22] Items included in the NSCS are skin redness, swelling and visible lesions, each receiving a score ranging from 1 (optimal) to 3 (total score ranging 3-9). The NSCS was determined before placement and after removal of the belt. Finally, the ability of using the belt as a cardiorespiratory monitor was explored by comparing the trend in HR and RR between the belt and CI.

Data analysis

dEMG and CI data were synchronised in time and resampled to obtain equal signal lengths. The time signal drift was present in the raw dEMG signal after placing the belt was determined manually. From the raw data, a respiratory waveform was obtained using data handling as previously described (see Figure 2).[6] In short, baseline data was first order high-pass filtered (cut-off frequencies of 15 Hz and 20 Hz [6,23]) to remove offset and signal drift (Figure 2(a)). Second, a copy of the filtered signal was rectified and smoothed by low pass filtering (cut-off: 15 Hz) to ease the detection of the QRS-complexes, using a peak follower (explained in the online supplement). The QRS-complexes and P-waves (at a fixed distance from the QRS-complex) were gated out (Figure 2(b)). Afterwards, residual cardiac interference was filtered out with high-pass filtering with a cut-off of 30 Hz [6] and the gates were filled with a copy of previous data (Figure 2(c)). The final respiratory waveform was obtained after smoothing of the signal by moving average filtering (Figure 2(d)).

For CI, only the numerical HR- and RR-values were used as we assumed that when a reliable HR or RR was provided, the corresponding waveforms were of acceptable quality. Erroneous and extreme HR- and RR-values in CI, caused by inability of the CI algorithm to calculate these values, were detected using a threshold of 400 beats/min (bpm) and 400 breaths/min, respectively (%HR error and %RR error of the total signal length).

For dEMG, the obtained ECG (filtered raw dEMG) and respiration waveform were used. Here, lead-off and BLE (%lead-off and %BLE of the total signal length) were determined. In addition, large signal artefacts in the respiration waveform were automatically detected using histogram analysis (online supplement).[24] The percentage of the respiration signal without lead-off, BLE and signal artefacts divided by the total signal length was referred to as %stable data.

To obtain more insight in the cause of the signal errors and artefacts, we analysed the percentage of the HR error, RR error, lead-off and BLE that occurred during clinical handling and kangaroo care. Moreover, the percentage of stable data during these episodes was described as well.

All errors described above were removed from the CI and dEMG signals to obtain paired stable data. Moreover, in the respiration waveform measured with the belt and the numerical RR-values of CI, the detected artefacts were removed. For CI, the average of the numerical HR and RR-values was calculated per minute. In the cleaned belt data, QRS-complexes and breaths were detected to calculate the minute average HR and RR. To compare the HR and RR measured with the belt and CI over time, a trend plot was made for the HR and RR for both techniques. To visualise 72 hours of data, an average HR and RR for all available subjects was calculated every 10 min. All data analysis was performed in Matlab (v2019b, MathWorks, USA) using a batch analysis.

Statistical analysis

All parametric data were presented as mean \pm standard deviation (SD) and non-parametric data as median (interquartile range (IQR)). An explorative comparison of the HR and RR trend measured with the belt and CI was performed using the intraclass correlation coefficient (ICC) and the percentage of time with ≤ 5 bpm or breaths/min deviation. As this was an exploratory study assessing a new technique of cardiorespiratory monitoring, performing a formal power calculation was not possible.

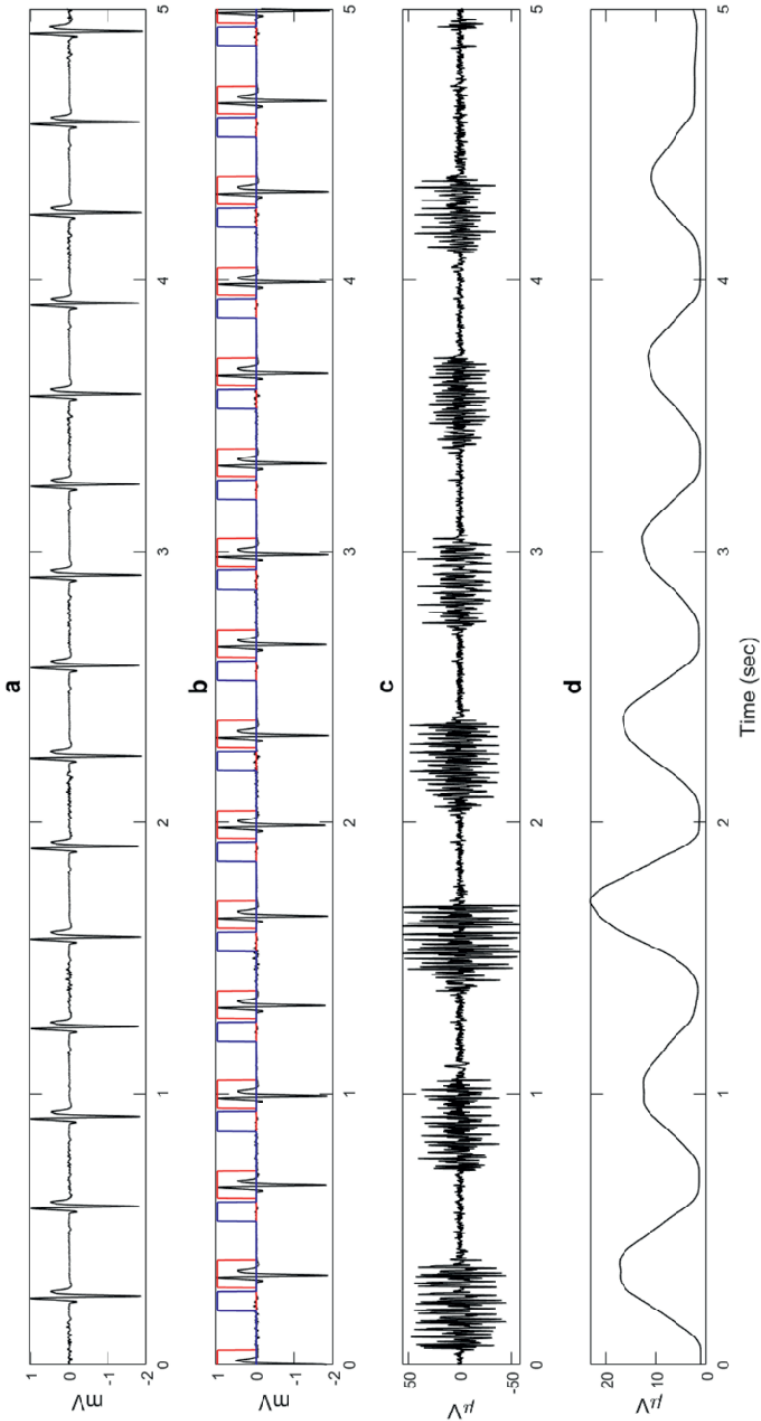


Figure 2 - Steps to obtain a respiratory waveform out of the raw diaphragm activity signal measured with transcutaneous electromyography (dEMG). a: the raw dEMG signal after high-pass filtering to remove the offset and drift; b: the shifted (due to delay caused by QRS-detection) raw dEMG signal with the gates around the detected QRS-complexes and P-waves (at a fixed distance); c: the result after gating and filling with a copy of previous data; d: the respiratory waveform after rectification and moving average filtering.

Results

In total, 24 infants were included of whom two were transferred to another hospital before starting the measurement and in one case parents withdrew consent. In one infant the measurement could not be started due to technical issues, as the receiver module was not detected by the personal computer (this was solved by updating the USB drivers). Finally, one infant on high-frequency oscillatory ventilation was excluded because there was too much disturbance of the CI signal, making a comparison between the techniques impossible. The final analysis was therefore based on measurements of 19 infants with a median GA of 27.3 weeks and birth weight of 950 g (Table 1). All infants were on non-invasive respiratory support, with the majority receiving nasal continuous positive airway pressure (nCPAP). The median measurement time was 27.8 (23.3-49.3) hours. Except for one infant, all infants were measured with belt size 2. One measurement was stopped prematurely due to clinical deterioration of the infant. In one measurement the belt shifted towards the nipples (weight at the start of the measurement was 1225 g, size 2 belt) and in another measurement 17 hours were not recorded due to an empty sensor battery leading to a BLE.

Table 1 - Patient characteristics

	n=19
Gestational age (weeks)	27.3 (26.4-29.6)
Birth weight (g)	950 (843-1225)
Post-menstrual age at the start of the measurement (weeks)	30.9 (30.0-31.9)
Weight at the start of the measurement (g)	1240 (960-1435)
Female/Male gender, n(%)	10 (52.6) / 9 (47.4)
Nipple distance (cm)	5.0 (5.0-6.3)
Apgar 5 min	8 (6-8)
Caffeine, n(%)	16 (84.2)
Doxapram, n(%)	1 (5.3)
Mode of respiratory support, n(%)	
nIPPV	1 (5.3)
nCPAP	14 (73.7)
HFNC	3 (15.8)
None	1 (5.3)

All continuous values are expressed as median (interquartile range). Categorical values are expressed as n(%). nIPPV: nasal intermittent positive pressure ventilation, nCPAP: nasal continuous positive airway pressure, HFNC: High Flow Nasal Cannula.

For CI, we identified erroneous HR-values in 0.1% (IQR 0.1%-0.3%) of recording time and erroneous RR-values in 0.1% (IQR 0%-0.5%) of time. Of the HR errors, 34.5% (IQR 10.3%-52.5%) occurred during clinical handling and 15.6% (IQR 0%-56.8%) during kangaroo care. For RR errors, these percentages were respectively 23.4% (IQR 6.5%-68.6%) and 1.7% (IQR 0%-36.1%).

The time a signal drift was present in the raw dEMG signal varied between subjects with a median time of 30 minutes (IQR 0-60). In all measurements a respiratory waveform could be obtained from the dEMG data directly after applying the belt. A median of 0.5% (IQR 0.1-1.6) of time lead-off and 0.3% (IQR 0.1-0.9) of time BLE was observed in the belt measurements. Higher lead-off times were observed in one infant with subcostal retractions, resulting in an upward movement of the belt, and in another infant measured with a size 1 belt with closely spaced electrodes leading to a relative stiff part in the belt. Of the lead-off errors, a median percentage of 17.6% (IQR 13.2-65.9) occurred during clinical handling and 2.9% (IQR 0-10.6) during kangaroo care. For BLE these percentages were 17.7% (IQR 3.9-34.8), and 37.9% (IQR 9.3-86.0) respectively. No HR- or RR-values >400/min were observed. When removing lead-off, BLE and large signal artefacts, a median percentage of 76.5% (IQR 69.3-80.0) of the respiration waveform measured with the belt consisted of stable data. Comparable results were observed during kangaroo care (74.4%, IQR 61.2-80.2) and clinical handling (72.6%, IQR 66.2-76.3).

All infants tolerated the belt well and no skin lesions were observed after removal. The median NSCS was 3 (IQR 3-3) in all subjects before the measurement and 3 (IQR 3-4) after the measurement was completed. In five infants the NSCS was 4 after the measurement, caused by temporary redness of the skin.

In Figure 3, the trend plot of the HR and RR for CI and the belt is displayed. The mean trend in HR measured with the belt followed CI closely with an ICC of 0.98 and 98.6% of the data being within 5 bmp from CI. RR showed more variance between the values measured with the two devices, where the belt often showed lower values than CI. Still a similar RR trend over time was observed with an ICC of 0.81 and 72.2% of the data being within 5 breaths/min from CI.

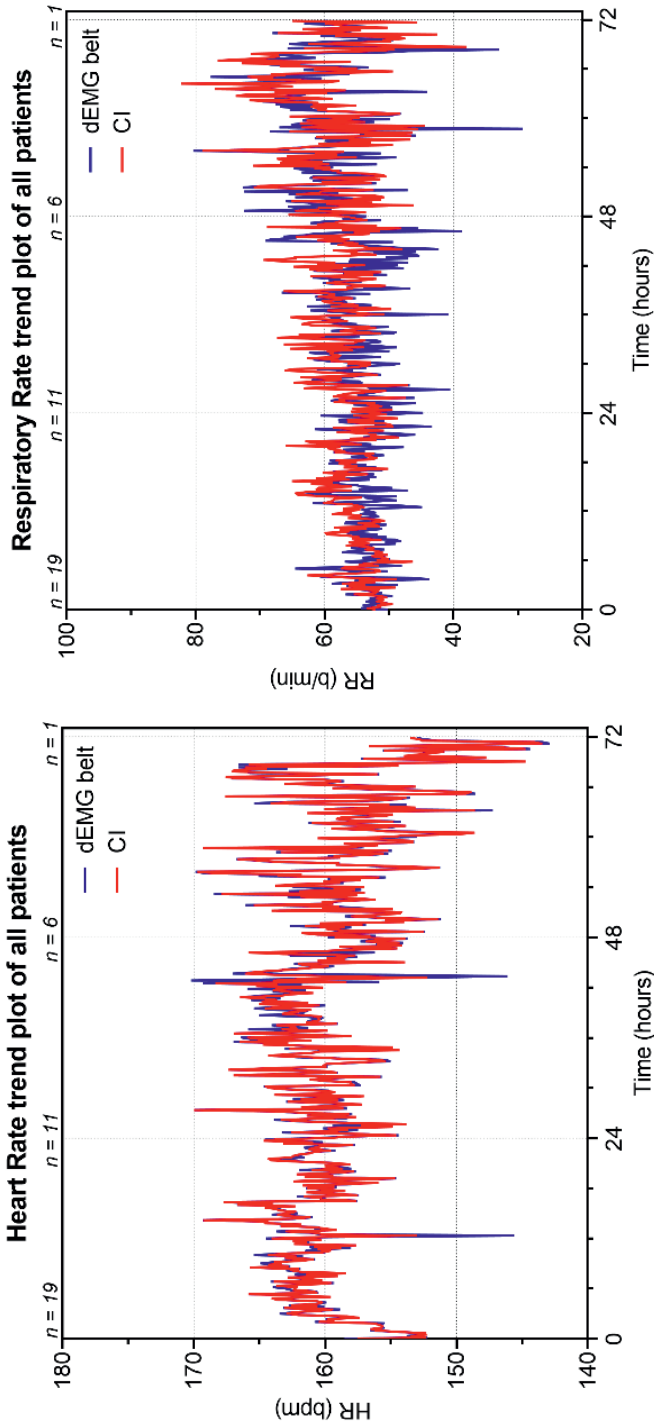


Figure 3 - The trend in heart rate (HR, left) and respiratory rate (RR, right) measured with the dEMG belt in blue and Chest Impedance (CI) in red. Each trend consists of the mean HR- or RR-value at 10-min intervals of all measured subjects. The number of subjects (n) on each measurement day is presented above the graphs. dEMG: transcutaneous electromyography of the diaphragm. Note: As errors and large signal artefacts are removed in the data, the patients included per time point could vary.

Discussion

To our knowledge, this is the first study evaluating a wireless belt with incorporated dry electrodes to measure diaphragm activity with dEMG in infants. The results show that it is feasible to measure the electrical activity of the diaphragm in a skin-friendly fashion. The loss of data was limited and the trends in HR and RR measured with the belt were comparable to CI.

Before moving to clinical validation and implementation of cardiorespiratory monitoring, it is important to first test the feasibility of the belt. This step is required, because there are certain technical pitfalls associated with using a wireless system with dry electrodes, such as signal drift, loss of skin contact (lead-off), and loss of Bluetooth connection. Drift was observed in the obtained raw dEMG signal. It is caused by dry electrodes requiring time to reach an impedance equilibrium, which is facilitated by perspiration filling the gap between skin and electrode.[21] The duration of the drift varied between infants, possibly due to a varying skin-electrode contact, skin condition or humidity/temperature settings of the incubator. Still, in each measurement a respiratory waveform could be obtained from the raw dEMG directly after applying the belt. Another risk in using dry electrodes, is the occurrence of lead-off. Lead-off is inherent to using dry electrodes as these require an external force to ensure skin-contact which may be insufficient if for example subcostal retractions or movement is present.[25,26] This was also confirmed in our study, showing that lead-off was often associated with the position of the infant, abdominal distention, subcostal retractions and the stiff part consisting of closely spaced electrodes in belt size 1 not continuously making adequate skin contact. Frequently checking the belt's location (at the height of the diaphragm) seemed to minimize lead-off. Fortunately, the percentage of lead-off in each measurement was small and these errors were mostly short in duration and resolved spontaneously. Another error related to the wireless design of the belt is inadequate Bluetooth connection (BLE), which may be caused by an empty sensor battery, blocking of the sensor, or too much distance between sensor and receiver.[27] Reassuringly, our study shows that BLE was only observed in <1% of the measurement time. It is unlikely that alternatives for Bluetooth, such as Wi-Fi, ZigBee and radio-frequency identification will yield better results.[28] These wireless techniques also have several disadvantages such as increased power consumption, susceptibility to interference from other devices, and a limited allowed distance between sensor and receiver.[28]

The signal stability of the HR measured with the belt was similar to CI, as the occurrence of errors in both techniques was small and comparable. Regarding respiration, in approximately 77% of the time stable data were obtained with the belt, which was lower than the percentage of time CI produced correct RR-values. However, it is important to emphasize that, in contrast to the dEMG data, only numerical CI data of RR were screened for errors and not the corresponding respiration waveform. It is very likely that this

difference in analysis explains, in part, the difference in RR stability time. Previous studies showed a similar amount of stable dEMG data in the NICU [7] and the DR [29] using adhesive electrodes and a slightly lower percentage of CI stability.[7,29]

To obtain more insight in the cause of instable data and errors, we studied its occurrence during kangaroo care and clinical handling as well. We observed that during clinical handling and kangaroo care the percentage of stable data was similar to total measurement time. The percentage of the errors that occurred during clinical handling and kangaroo care varied between infants, which is probably best explained by differences in, for example, subcostal retractions or movement leading to lead-off or errors in HR and RR. BLE and HR errors seemed more related to clinical handling and kangaroo care compared to lead-off and RR errors.

It is important to study the skin-friendliness of the belt in this population with an immature skin that is susceptible to trauma. The likelihood of developing iatrogenic skin injury increases with a lower gestational age and with a longer duration of belt application.[14] Our results indicate that the use of dry electrodes over a median time of 27.8 hours in preterm infants does not lead to significant skin defects.

Eventually, the intended use of the belt is cardiorespiratory monitoring of neonates. Although validation was not the aim of this study, we performed a first explorative analysis to study the ability to monitor the HR and RR trend with the belt. The results are promising with comparable trends between the belt and CI, which is consistent with the findings of a previous study in the NICU using adhesive electrodes.[7]

Limitations

Several limitations should be kept in mind when interpreting the results. First, CI was used as the reference for the RR, but as mentioned before this technique can provide inaccurate data. Still, CI is the clinical standard and the current setup did not enable the incorporation of additional respiratory markers (e.g. flow).[3] Second, only clinically stable preterm infants were included in this study. Whether the results will be similar in less stable patients has yet to be determined. Moreover, in case of noise or low voltage data, the peak detection could become suboptimal. Finally, the belt seems to be a promising wireless and skin-friendly cardiorespiratory monitoring device. However, the belt cannot be used in the entire NICU population as for example skin lesions at the belt location (stoma, drain) may hinder belt placement.

Clinical implications

Our findings are encouraging and show that it is feasible to measure dEMG and thereby HR and RR with a non-adhesive and wireless belt. However, improvements can be made, such as making the belt at the location of the electrodes more flexible [30-32], using an adaptive gain (i.e. a gain that increases when signal strength decreases) to improve breath detection when measuring a low voltage signal, and automating the marking of invalid HR- and RR-values. A larger validation study investigating the ability to use the belt with its embedded software as a cardiorespiratory monitor is required to confirm if the belt could replace CI. In such a validation study, the agreement in HR and RR, critical events (e.g. bradycardia, tachypnea), the amount of reliable data and usefulness of the data during clinical scenario's (e.g. kangaroo care, feeding) should be studied. In addition, the performance of the belt sizes other than size 2 should be further investigated.

Conclusion

This study shows that it is feasible and safe to measure diaphragm activity by dEMG with dry electrodes incorporated in a wireless belt in preterm infants. HR and RR could be reliably monitored over time. Future studies should aim to validate the belt compared to standard cardiorespiratory monitoring.

Ethical statement

This study was conducted in accordance with the principles embodied in the Declaration of Helsinki and in accordance with local statutory requirements. All parents gave written consent for participation of their child in our study.

Competing interests statement

The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest. However, the authors did receive an in-kind contribution of Bambi Medical B.V. (i.e. the belts, sensor and receiver modules and the personal computer) to fulfil the measurements.

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Online supplement

Detection of QRS-complexes

The filtered input signal was rectified and smoothed by low pass filtering (cut-off: 15 Hz) to ease QRS-detection. A peak follower equalled this signal when it increased, and thus a QRS-complex was present and was detected, and exponentially decreased after the peak in the smoothed signal until it met the next QRS-complex.

Histogram analysis to detect and remove large signal artefacts

Large signal artefacts were detected by using a histogram analysis. In this analysis a histogram of the respiratory waveform measured with the belt was made per hour. With the histogram bins were made comprising all microvoltages of the respiratory waveform. An artefact threshold was determined using two requirements:

1. The bin of the histogram had to consist of a minimum amount of data (5% of the one-hour data). The bin containing the highest microvoltages that satisfied this requirement was used for the second requirement.
2. The bin had to be within the median of the data + 75% of the entire distribution of the histogram to ensure that outliers in the data (i.e. caused by movement or clinical handling of the infant) were marked.

Around the detected artefacts 5 seconds of data before and after this artefact was removed. This algorithm was performed three times for the belt data to subsequently detect and remove smaller outliers around large artefacts.