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## ABSTRACT

**Objective** To assess feasibility of transcutaneous electromyography of the diaphragm (dEMG) as a monitoring tool for vital signs and diaphragm activity in the delivery room (DR).

**Design** Prospective observational study.

**Setting** Delivery room.

**Patients** Newborn infants requiring respiratory stabilisation after birth.

**Interventions** In addition to pulse oximetry (PO) and ECG, dEMG was measured with skin electrodes for 30 min after birth.

**Outcome measures** We assessed signal quality of dEMG and ECG recording, agreement between heart rate (HR) measured by dEMG and ECG or PO, time between sensor application and first HR read-out and agreement between respiratory rate (RR) measured with dEMG and ECG, compared with airway flow. Furthermore, we analysed peak, tonic and amplitude diaphragmatic activity from the dEMG-based respiratory waveform.

**Results** Thirty-three infants (gestational age: 31.7±2.8 weeks, birth weight: 1525±661 g) were included. 18%±14% and 22%±21% of dEMG and ECG data showed poor quality, respectively. Monitoring HR with dEMG was fast (median 10 (IQR 10–11) s) and accurate (intraclass correlation coefficient (ICC) 0.92 and 0.82 compared with ECG and PO, respectively). RR monitoring with dEMG showed moderate (ICC 0.49) and ECG low (ICC 0.25) agreement with airway flow. Diaphragm activity started high with a decreasing trend in the first 15 min and subsequent stabilisation.

**Conclusion** Monitoring vital signs with dEMG in the DR is feasible and fast. Diaphragm activity can be detected and described with dEMG, making dEMG promising for future DR studies.

## What is already known on this topic?

- Vital signs monitoring is essential in the delivery room (DR).
- Most preterm infants need respiratory support in the DR.
- Current monitoring techniques provide very little information on breathing effort of the infant, which is essential to titrate respiratory support.

## What this study adds?

- Transcutaneous electromyography of the diaphragm is a feasible technique to monitor vital signs in the DR.
- Diaphragm activity might be a useful indicator of breathing effort and stabilisation of infants in cardiopulmonary transition and could potentially improve respiratory support titration.

## INTRODUCTION

During pulmonary transition at birth, high transpulmonary pressures are created during spontaneous breathing,[1] necessary for lung liquid clearance, lung aeration and establishing pulmonary gas exchange.[2–4] Animal studies have already demonstrated that breathing effort is essential for successful pulmonary transition, but studies substantiating this in newborns are scarce.[2 3]

In up to 60% of preterm infants, cardiopulmonary transition is hampered, requiring respiratory support.[5 6] The modality most often used in the delivery room (DR) is nasal continuous positive airway pressure (CPAP), which facilitates lung fluid clearance, stabilises lung aeration and prevents re-entry of interstitial liquid in the alveolar compartment during expiration.[7 8] When CPAP alone is not sufficient for adequate oxygenation and ventilation, supplemental oxygen and/or positive pressure ventilation (PPV) is provided.[9] It is considered essential to individualise the level of respiratory support, because both too little and too much support may injure the lungs.[10]

Monitoring the infant's vital signs and response to treatment is essential when titrating respiratory support in the DR. International guidelines recommend to monitor oxygen saturation and heart rate (HR) using pulse oximetry (PO) and ECG.[9] Respiratory rate (RR) can be acquired by chest impedance (CI) changes, based on ECG monitoring, and observation of chest excursions, although these techniques might sometimes be inaccurate.[11–13] Improved accuracy in monitoring RR is achieved with flow measurement at the airway opening, which is therefore increasingly used in the DR, often with a respiratory function monitor (RFM).[11 14–16] Interestingly, breathing effort generated by the diaphragm is not monitored as up to now this was not deemed feasible in the DR.

Transcutaneous electromyography of the diaphragm (dEMG) is a feasible technique in the neonatal intensive care unit (NICU) to monitor HR, RR and, most importantly, diaphragm activity.[17] Previous studies have shown that dEMG is able to detect changes in diaphragm activity, which is considered a surrogate of breathing effort, in response to changes in respiratory support.[18 19] Having this information on diaphragm activity available in the DR might greatly enhance our understanding of the physiology of pulmonary transition and also improve our ability to titrate respiratory support to the individual patient.

However, transcutaneous dEMG has never been studied in the DR where environmental and patient conditions are different from the NICU. Therefore, the aim of this study is to assess the feasibility of monitoring vital signs and diaphragm activity with transcutaneous dEMG in the DR.

## METHODS

This prospective observational study was conducted in the Emma Children's Hospital in Amsterdam and the Willem-Alexanders Children's Hospital in Leiden with approval from the institutional review boards (METC AMC, ABR registration, NL64266.018.18).

### Population

Infants born with a gestational age >26 weeks and requiring routine monitoring of vital signs in the DR were included unless they had a congenital abnormality. Every effort was made to obtain written informed consent antenatally. If this was not possible (unexpected delivery), deferred consent to use the acquired data was asked.

### Study procedures

Directly after birth, cord-clamping was delayed for 30–60 s and CPAP (5 $cmH_2O$) was started in preterm infants <32 weeks or in case of insufficient breathing in more mature infants. Initial oxygen level was 30% for preterm infants <32 weeks and 21% for older infants. A PO sensor (Nellcor, Covidien, USA, or SofTouch sensor, Masimo, USA) was placed around the right wrist or hand to measure $HR_{PO}$ and oxygen saturation. To maintain clinical routine as much as possible, three ECG electrodes (13 953D, Philips, the Netherlands) measuring $HR_{ECG}$ and RR (based on CI, $RR_{CI}$) were only placed on the infant's chest if deemed necessary by the treating physician. As part of standard care, an RFM (NewLifeBox, Applied Biosignals, Germany) recorded airway pressure, flow and mask leak with a flow sensor (VarFlex, Vyaire Medical, USA), at the airway opening. Supplemental oxygen was measured with an oxygen sensor (AX300, Teledyne analytical instruments, USA). A video camera was placed above the bed to derive the timing of sensor and electrode placement.

In addition to this standard monitoring protocol, diaphragm activity was measured with transcutaneous dEMG. Three skin electrodes (H59P, Covidien, Ireland) were placed on the infant's chest. Two bilaterally in the midclavicular line at the costal margin and one on the sternum, as a reference (figure 1). The electrodes were connected to the Dipha-16 signal amplifier (Macawi Medical Systems, Demcon, the Netherlands), which sampled at 1 kHz, after which data were sent wireless to the RFM at 500 Hz (averaged). Measurements continued until 30 min after birth or up to transfer to the ward. The dEMG electrodes were removed before transfer. All data were stored at 500 Hz for offline analysis.

### Data analysis

The following baseline characteristics were collected: use of antenatal steroids, gestational age, birth weight, sex, mode of delivery, Apgar score and maximal level of respiratory support

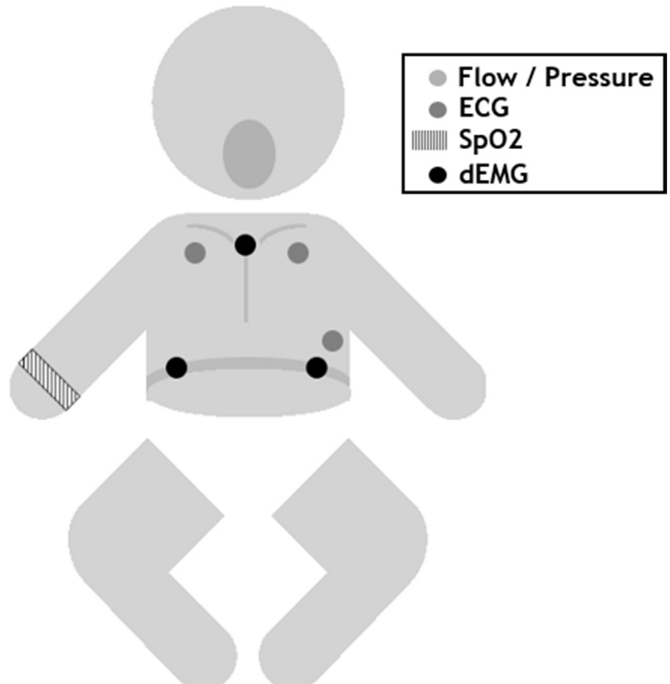


**Figure 1** Schematic illustration of the sensors and electrodes connected to the infant. dEMG: electromyography of the diaphragm; $SpO_2$, oxygen saturation.

(positive end-expiratory pressure, peak inflation pressure and oxygen demand) during transition.

To measure feasibility of dEMG, the agreement in vital signs, detection speed and amount of data loss were compared between dEMG and the other monitoring techniques. First, $HR_{EMG}$ was derived from the 25 Hz high-pass filtered raw dEMG signal (to remove offset) and compared with $HR_{ECG}$ and $HR_{PO}$, derived from the raw ECG an PO waveforms. In addition, the time delay (Δt) between sensor placement of each device and the first numerical HR read-out was calculated (ie, detection speed). Subsequently, the raw dEMG signal was postprocessed (as previously described[20]). The signal was low-pass filtered, and cardiac activity was removed with the gating technique.[21] The cardiac-free dEMG signal was full-wave rectified, and the root mean square value was calculated to retrieve a dEMG-based respiratory waveform to determine $RR_{EMG}$. Both $RR_{EMG}$ and $RR_{CI}$ were compared with the RR based on airway flow ($RR_{flow}$), which was considered the gold standard. Third, artefactual periods with signal spikes or electrode disconnection were determined visually and the percentage of dEMG data loss ($\%EMG_{loss}$) and ECG data loss ($\%ECG_{loss}$) was calculated.

Finally, to test the ability to measure diaphragmatic activity, we analysed the respiratory waveform in the first 30 min after birth. Every 5 min, a 1 min interval was selected. Start and end of the respiratory cycle was detected in these segments, and the average peak (end-inspiratory, $dEMG_{peak}$) and tonic (end-expiratory) activity ($dEMG_{ton}$) were determined. The inspiratory amplitude ($dEMG_{amp}$) of the respiratory cycle was calculated by subtracting $dEMG_{ton}$ from $dEMG_{peak}$. Although not the focus of this study, we performed an exploratory analysis on the trend of the dEMG parameters after birth. Furthermore, we compared $dEMG_{peak}$ between infants who received only CPAP and those receiving inflation breaths and/or non-invasive PPV. Offline analysis was done with a custom-made algorithm in MATLAB (V.2018b, MathWorks, USA).

**Table 1** Baseline characteristics

| | n=33 |
|---|---|
| Gestational age (weeks) | 31.7±2.8 |
| Birth weight (g) | 1525±661 |
| Male gender (%) | 18 (55) |
| C-section (%) | 25 (76) |
| Full course antenatal corticosteroids (%) | 30 (91) |
| Apgar at 1 min | 7 (4–8) |
| Apgar at 5 min | 8 (8–9) |
| Respiratory support | n=31 |
| CPAP, PEEP level (cm$H_2O$) | 5 (5–6)* |
| PPV, PIP level (cm$H_2O$) | 20 (20–20)† |
| Maximum oxygen demand (%) | 50 (30–65) |

All continuous values are expressed as mean±SD or median (IQR). Categorical variables are expressed as n (%).
*n=31.
†n=13.
CPAP, continuous positive airway pressure; C-section, caesarean section; PEEP, positive end-expiratory pressure; PIP, peak inflation pressure; PPV, positive pressure ventilation.

**Table 2** Agreement in vital signs measured with different devices

| Comparison | ICC (confidence interval) | Mean difference (LOA) |
|---|---|---|
| Heart rate (HR) | | |
| $HR_{EMG}$ vs $HR_{ECG}$ | 0.91 (0.91 to 0.92)* | −1.3 bpm (−14.5 to 11.9) |
| $HR_{EMG}$ vs $HR_{PO}$ | 0.81 (0.81 to 0.82)† | 0.01 bpm (−21.6 to 21.6) |
| Respiratory rate (RR) | | |
| $RR_{EMG}$ vs $RR_{flow}$ | 0.49 (0.40 to 0.56)† | −3.9 breaths/min (−25.2 to 17.4) |
| $RR_{CI}$ vs $RR_{flow}$ | 0.25 (0.17 to 0.31)* | −5.2 breaths/min (−31.8 to 21.4) |

*n=24.
†n=30.
CI, chest impedance; ECG, electrocardiography; EMG, electromyography; HR, heart rate; ICC, intraclass correlation coefficient; LOA, limit of agreement; PO, pulse oximetry; RR, respiratory rate.

## Statistical analysis

Continuous data were expressed as mean±SD or median (IQR) depending on their distribution. Based on previous studies, a convenience sample of 30 infants was considered to be appropriate to investigate dEMG feasibility in the DR.[22 23] All infants were expected to have PO recordings available, and ECG use was estimated to be at least 50%. Measurements in which dEMG electrodes were placed more than 5 min after birth were excluded because too much time of the transition was missed.

Agreement of vital signs between different techniques was assessed with the intraclass correlation coefficient (ICC) and Bland-Altman analysis (limits of agreement (LOA)). dEMG parameters were compared over time with repeated measurements analysis of variance with post hoc Bonferroni test or with the Friedman test with post hoc Dunn's test. All statistical analyses were done in SPSS (V.25, IBM, USA). A p value <0.05 was considered statistically significant.

## RESULTS

Thirty-four infants were included of whom one was excluded because the placement of the dEMG electrodes could not be realised in the first 5 min. Therefore, diaphragm activity was described in 33 infants. PO data were only available in 30 infants due to an error in data storage in three infants. In 24 (73%) infants, ECG data were available. RR comparison between dEMG and flow was possible in 30 infants because two did not require respiratory support and in one flow was not measured. Baseline characteristics are presented in table 1.

## Feasibility of electromyography for monitoring

The electrodes for dEMG were placed on average 2:40 min±54 s after birth, and no skin lesions were observed. The $\%EMG_{loss}$ and $\%ECG_{loss}$ was, respectively, 18%±14% and 22%±21%. Based on the video recording, the main reasons for loss of signal quality were electrode detachment, spontaneous movements or clinical handling. The median Δt between sensor placement and first HR read-out was comparable for the three devices. 22 (IQR 11–41), 17 (IQR 15–33) and 10 (IQR 10–11) s for ECG, PO and dEMG, respectively (non-significant).

Table 2 shows the ICC and the mean difference (LOA) for HR and RR between dEMG and the other monitoring devices. HR agreement between dEMG and ECG was high (ICC 0.91) and moderate for dEMG versus PO (ICC 0.81). Comparison of $RR_{EMG}$ and $RR_{flow}$ showed modest agreement (ICC 0.49) and $RR_{CI}$ compared with $RR_{flow}$, low agreement (ICC 0.25). The mean difference for HR and RR was modest, but the LOA showed a clear variability for HR and RR detection.

## Diaphragm activity during transition

Figure 2 shows the exploratory analysis of $dEMG_{peak}$, $dEMG_{amp}$ and $dEMG_{ton}$ over time. In general, these parameters show a (non-significant) gradual decrease in diaphragmatic activity in the first 10–15 min of life, after which the activity seemed to stabilise.

Figure 3 shows the explorative analysis of the difference in $dEMG_{peak}$ over time in infants who received either CPAP (n=18) or PPV (n=13). Diaphragm activity tended to be lower in infants who received PPV, compared with CPAP alone (not statistically significant).

## DISCUSSION

This study is the first to describe the use of transcutaneous dEMG as a cardiorespiratory monitor in the DR. Our study shows that dEMG is feasible to provide data on HR, RR and diaphragm activity in newborn infants during postnatal pulmonary transition.

Visual assessment of the signal revealed that a reassuring 80% of the dEMG recording was deemed suitable for signal analysis. Like all other monitoring signals (ECG and PO), dEMG recording was disturbed by patient movement, clinical handling and electrode detachment. The latter may be improved by using preset electrodes,[24] or an electrode belt using non-adhesive electrodes, a technique currently under investigation.[25]

HR registration with dEMG showed a high level of agreement with standard ECG and a similar HR detection speed. This suggests that dEMG is feasible as an alternative for ECG in the DR. Monitoring RR with either dEMG or ECG (which registers CI) was less accurate and showed more variability compared with the RR based on flow at the airway opening. The accuracy of dEMG-based RR was higher in the study by Kraaijenga *et al*,[17] who used the same dEMG signal acquisition protocol, but their comparison of dEMG was with CI and not with flow. Furthermore, clinical handling during their study period was minimal, which was not possible in the acute setting of the DR where patient handling is necessary. As clinical handling can lead to electrode detachment (dEMG) and/or mask displacement (flow), it is not surprising that RR agreement was lower in this setting.

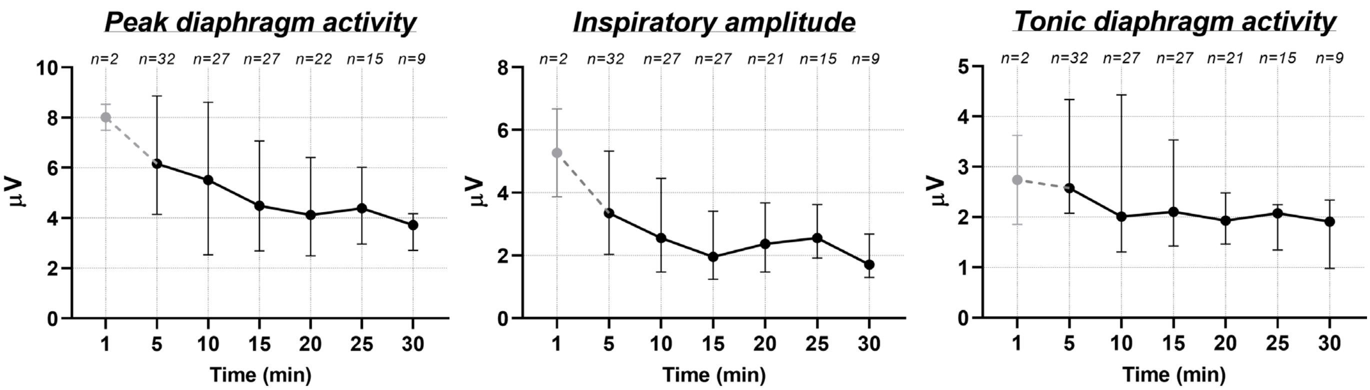


**Figure 2** Average peak, amplitude and tonic diaphragm activity per breath in newborn infants measured with electromyography from birth to 30 min after birth. The numbers on top of the graph indicate the number of infants of whom an average could be determined for that minute interval. Markers at 1 min are dashed due to the small sample size.

The good signal quality was confirmed by the fact that the commonly used dEMG variables to assess diaphragm activity could be determined. This allowed us to explore diaphragmatic activity during the first 30 min after birth. The data suggest that diaphragm activity tends to drop in the first 10–15 min and then stabilises. This pattern is consistent with the study of Oda *et al*,[26] who described a decreasing diaphragm activity as well in the first 2 hours of life. However, they recorded diaphragm activity with an oesophageal catheter. The currently used transcutaneous dEMG is non-invasive, less expensive and does not require interruption of CPAP support.

Our finding that diaphragmatic activity is initially high during both the inspiratory ($dEMG_{peak}$) and expiratory ($dEMG_{ton}$) phase of spontaneous breathing seems to support the suggestion that the diaphragm is a key component in the transition. During inspiration, it creates the necessary inspiratory pressure to clear fluid and aerate the lung, and it remains active during expiration to preserve lung aeration. Experimental studies have shown that the process of lung aeration takes up to 5–10 min, which matches the stabilisation time we found in diaphragmatic activity.[3 7 27] The higher diaphragm activity also aligns with the fact that most preterm infants breathe and cry spontaneously immediately after birth,[28] for which diaphragmatic activity is essential.

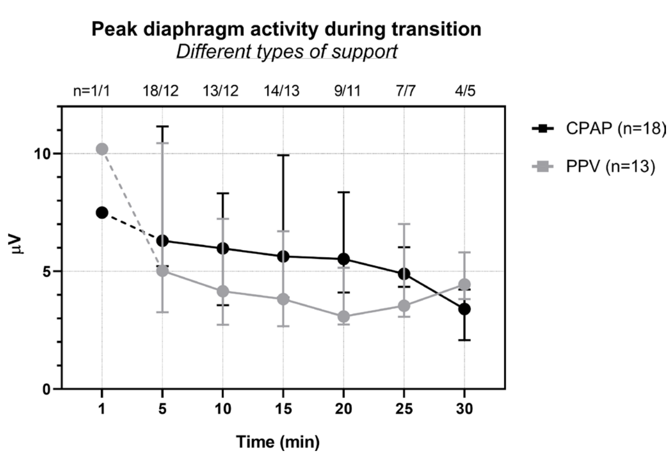


**Figure 3** Average peak diaphragmatic activity in infants who received continuous positive airway pressure (CPAP; black, bold line) versus those who received positive pressure ventilation as well (PPV; grey line). Each bar represents the average at that minute interval. The numbers on top of the graph are the number of infants of which an average could be determined for that interval noted as CPAP/PPV. Markers at 1 min are dashed due to the small sample size.

Exploratory analysis showed a trend towards lower diaphragm activity in infants supported with PPV compared with CPAP alone. The origin of this finding is unclear. First, changes in diaphragm position due to alteration in chest[29] and abdominal dimensions can influence dEMG signal strength,[23 30] but this effect is expected to be similar in all infants. Second, providing more respiratory support with PPV could unload the diaphragm.[19] Third, diaphragm activity may be lower in the first place in infants that need PPV, due to a lower respiratory drive.[31] These mechanisms suggest that dEMG could provide valuable information on which patients need more respiratory support and if this support is effective. The technology is easily accessible and, as shown, can be linked to an RFM. We would like to emphasise that the data on diaphragmatic activity obtained in these explorative analyses should be interpreted with caution as the findings are based on a small sample size and the differences were not statistically significant. Future studies need to confirm or refute our findings.

Our study has several limitations worth mentioning. First, the included infants did not receive invasive respiratory support. It is unclear how the signal quality will change in infants with more severe respiratory distress. Second, the sample size did not allow for subdivision based on mode of delivery and use of antenatal steroids.[32] Third, the contribution of surrounding muscles to dEMG signal strength (cross-talk) cannot be ruled out entirely.[33 34] Although its impact is expected to be limited in (immature) infants,[35 36] it is a technical limitation of dEMG. Furthermore, the electrodes were placed several minutes after birth and part of the pulmonary transition may have been missed. Including these first minutes might change our results. However, this delay is difficult to overcome as it is partly inherent to the guidelines, recommending delayed cord clamping up to 1 min after birth.[37] Fifth, the influence of environmental differences between the centres on the results cannot be ruled out. Lastly, the dEMG algorithm was used offline and has to be validated in a real-time application.

## CONCLUSION

This study confirms the feasibility of transcutaneous dEMG in the DR. HR monitoring showed high accuracy, while RR monitoring is more prone to noise. Diaphragm activity can be monitored with dEMG providing information on breathing effort during transition. The results warrant further investigation of diaphragmatic activity in the DR, to better understand the respiratory physiology and optimise respiratory support.

**Contributors** RWvL, CGdW, FHdJ, GJH and AHvK made substantial contributions to the conception and design of the study. RWvL, EK and HS included infants in the study. RWvL and EK analysed the data. RWvL wrote the first version of the manuscript. All authors are acknowledged for their critical revision of the manuscript. All authors approved submission of the paper for publication

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**Competing interests** None declared.

**Patient consent for publication** Not required.

**Ethics approval** The institutional review boards of the Amsterdam UMC in Amsterdam and the Leiden University Medical Centre in Leiden (METC AMC, ABR registration, NL64266.018.18).

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**Data availability statement** Limited data are available on reasonable request. Unpublished data of the measurements in this cohort are only accessible to the authors of the paper. It is saved in a locked database.

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