

Clinical study shows that use of Monivent Neo100 significantly increases the quality of ventilation of newborns

The results of a larger clinical study in which Neo100 has been used were presented today at the Pediatric Academic Societies (PAS) annual meeting in Washington. The results showed that the quality of ventilation of newborns who needed respiratory support increased significantly with the use of Monivent's product. Excessive tidal volumes have previously been associated with an increased risk of brain injury and the study showed that high volumes could be reduced when using Neo100.

"That the results from the study show that using Neo100 significantly can increase the quality of ventilation of newborns is incredibly gratifying. Neo100 has been developed specifically for ease-of-use in the delivery room and our goal is to introduce the product as standard equipment in every delivery room to improve the care given to newborn babies", says Karin Dahllöf, CEO of Monivent.

Newborns who are not breathing at birth may require respiratory support where air is pumped into the baby's lungs. 3-6% of all newborns end up in this critical situation. Tidal volumes should be within a target range to avoid the risk of lung and brain damage. Estimation of volumes is currently mostly done through clinical assessment by the healthcare provider. Neonatal resuscitation is a complex and stressful situation as the caregiver assimilates and interprets a constant feedback of different physiological parameters. Monivent Neo100 has been developed for ease-of-use in the delivery room, is added to existing ventilation equipment and measures, among other parameters, the volumes given to the baby. The results of the clinical study, including 90 newborns, show that the use of Neo100 significantly increased the quality of ventilations by a higher percentage occurring within a target volume range. The equipment was used for newborn resuscitation in the delivery room and during elective intubation in the neonatal intensive care unit. The percentage of ventilations with tidal volumes within a target range was significantly higher in the intervention group where Neo100 was used (53.7%), than in the control group without feedback (37.3%). Excessive tidal volumes (defined as >8 ml/kg), which have been previously associated with an increased risk of brain injury, could be significantly reduced when Neo100 was used (10.9% compared to 29.5% in the control group). Furthermore, mask leakage could also be significantly decreased with the use of Neo100. The study was carried out at the Medical University Hospital in Vienna and the results were presented by Dr. Michael Wagner at the Pediatric Academic Societies (PAS) Annual Meeting.

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***Monivent AB** ("Monivent") develops, manufactures and sells medical devices in order to improve the emergency care provided to newborns in need of respiratory support at birth. About three to six percent of all newborns end up in this critical situation and healthcare professionals today lack good tools to determine how effective this manual ventilation is. Monivent has developed equipment that measure the airflow to the child directly in the face mask via a sensor module that sends data wirelessly to an external monitor. The caregiver thereby receives immediate feedback, which enables necessary adjustments to support an effective but at the same time gentle treatment. The company is also marketing a product for simulation-based training on manikins, building on the same technology as the clinical product. The clinical product, Monivent Neo100, is not available for sale in the United States.*