

Effectiveness and Acceptability of Bag-and-mask Ventilation with Visual Monitor for Improving Neonatal Resuscitation in Simulated Setting in Six Hospitals of Nepal

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ABSTRACT

Background: Improving the performance of health workers on neonatal resuscitation will be critical to ensure that the babies are effectively ventilated. We conducted a study to evaluate whether a bag-and-mask ventilation with monitor is effective in improving neonatal resuscitation practice in a simulated setting.

Methods: This is a cross-over design conducted in 6 public hospitals with 82 health workers of Nepal nested over a large scale stepped wedged quality improvement project. A one-day training on neonatal resuscitation was conducted. At the end of the training, participants were evaluated on the bag-and-mask ventilation performance in a manikin based on the tidal volume, positive end expiratory pressure and air leakage from the mask in two sessions (monitor displayed versus hidden). The comparison of the neonatal resuscitation performance with and without monitor displayed is calculated. We also conducted assessment of confidence with or without monitor of the health workers.

Results: Adequacy of ventilation using bag-and-mask was better when the health workers were displayed monitor (90%) vs without monitor (76%) ($p < 0.01$). The air leakage from the mask reduced when the monitor was displayed (12%) vs without (30%). The PEEP improved when the health workers used monitor as guide to conduct neonatal resuscitation in the manikin then without monitor displayed. The participants felt more confident performing ventilations during the visible sessions.

Conclusions: The ventilation function monitor helped participants to improve their ventilation skills through real-time feedback of important ventilation parameters. Clinical evaluation of needs to be done to assess the effectiveness of the device.

Keywords: Clinical performance; monivent neo; neonatal resuscitation; Nepal; ventilation monitor.

INTRODUCTION

The first minute after birth is critical for saving 10 million newborns who do not breathe at birth.^{1,2} Among the several cost-effective interventions to reduce intrapartum-related complications is effective newborn resuscitation at the time of birth.³ Intrapartum-related neonatal deaths can be reduced by 30% with resuscitation training.^{1,2} However, several observational studies have shown that skilled health providers failed to effectively ventilate non-crying babies at the time of birth.^{4,5} It is crucial to ensure adequate pressure and tidal volume

is given during resuscitation.⁶ Previous studies have shown benefits of using a ventilation function monitor to help health workers improve their resuscitation skills in both simulated and clinical settings,⁷⁻⁹ which also can reduce mask leakage and control tidal volume during resuscitation.¹⁰ Due to this, there have been initiatives to improve resuscitation and also decrease lung injuries.¹¹ Our study aimed to assess the effectiveness of use of ventilation function monitor (Monivent Neo) to improve the newborn resuscitation skill of health workers in a simulated setting.

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METHODS

A total of 82 participants were included for the study. The participants were from different clinical backgrounds and included clinical consultants, medical doctors, nurses and paramedics who were directly and indirectly involved in perinatal health care delivery services. The health workers were working in different perinatal units - maternity ward, neonatal intensive care unit, special newborn care unit, operation theatre, emergency ward and pediatric ward.

This was a nested study to a larger stepped wedge cluster randomized controlled trial to evaluate hospitals which were implementing Nepal Perinatal Quality Improvement Project.¹² This was a stepped wedge cluster randomized trial implemented in 12 public hospitals of Nepal covering an estimated 60,000 deliveries during the 12-month study period. The hospitals were randomly allocated into four wedges where each wedge had three hospitals within intervention delayed for 3 months in each wedge before moving on to the next wedge.

Variables included neonatal resuscitation, kangaroo mother care, infection management, delivered as part of an intervention package, allowing training of healthcare workers in the hospitals, skill drills and real-time monitoring of data. Outcomes include intrapartum and first-day mortality followed by health worker performance.

A randomized crossover design was implemented to evaluate this study in six hospitals where the larger quality improvement project has been initiated.

The sites were Western Regional Hospital, Nuwakot District Hospital, Mid-Western Regional Hospital, Prithvi Chandra Hospital, Rapti Sub-Regional Hospital and Koshi Zonal Hospital.

Monivent Neo Training Device - Monivent Neo training is an aid for simulation-based training of neonatal ventilation. The system includes face masks, sensor modules, charging station and a tablet.

The face mask had a constriction that generates a differential pressure relative to the flow through the mask. The sensor module measured the differential pressure and gauge pressure when connected to the face mask. The sensor module converts the differential pressure to flow. The flow was then integrated to volume. An algorithm detected start and end of ventilation and computed the ventilation parameters. The measured parameters were tidal volume (V_{Te}), Peak Inspiratory

Pressure (PIP), Positive End Expiratory Pressure (PEEP), air leakage and ventilation rate.

Tidal volume (V_{Te}) is the lung volume representing the normal volume of air displaced between normal inhalation and exhalation when extra effort is not applied.¹³

Peak inspiratory pressure (PIP) is the highest level of pressure applied to the lungs during inhalation.¹⁴ Positive end-expiratory pressure (PEEP) is the pressure in the lungs above atmospheric pressure that exists at the end of expiration.

The parameters were wirelessly transmitted and displayed on the tablet.

The data were stored in the tablet (iPad for this study) which can also be documented and analyzed.

Objective Structured Clinical Examination (OSCE) was used for the assessment of resuscitation skill of the health workers. The tool were developed by the American Academy of Pediatrics (AAP) for the HBB training.¹⁵ Besides OSCE, a Confidence Rating Scale tool was developed where they were asked regarding confidence on ventilation procedures during the sessions. An equipment evaluation tool was also used to get the perception of health workers on the ease of use, parameters and their feedback for improvement of the device. A Likert Scale¹⁶ was used to record their confidence. The tools were in English.

Before the assessment, all health workers were trained on HBB using *NeoNatalie*. The participants worked in groups where their partner assessed their ventilation skills using OSCE. After the OSCE, two trainers were allocated for the assessment who would demonstrate the process to all the participants, detailing the ventilation process, parameters and feedback system.

After the OSCE, the health workers were randomized using Blocked Randomization List to determine whether the health workers were in the visible or hidden group for the first ventilation attempt. The health worker then performed two ventilation attempts irrespective of which group s/he would fall in. After the first ventilation, the health worker filled the confidence evaluation sheet based on the group which they belonged. They were then given few minutes before they were enrolled for the second ventilation attempt.

Each participant was given sufficient time to prepare before ventilation. They were asked to check for

head extension, sealing of the mask and look for chest movement before they were recorded. No feedbacks were given during the hidden attempt.

The assessment was conducted in a separate room to maintain privacy of the participants and avoid any influencing factors affecting the participant's performance. Written informed consent was taken from each of the participants before the assessment. At the end of the assessment, results were shared with the participants to allow them to look at how they performed during each session.

Frequency distributions were used to demonstrate demographic characteristics of study participants. Cross-tabulations were done for confidence among participants during ventilation sessions during hidden versus visible sessions. Chi-square test (χ^2) was done to investigate the significance of difference between hidden and visible sessions with a level of significance measured through p-value ($p < 0.05$). All analysis was done using IBM SPSS Statistics version 23.

The ethical approval for the study was provided by Nepal Health Research Council (NHRC), the national governing body for research activities in Nepal. Written informed consent was taken from the health workers participating in the study.

RESULTS

The initial findings showed positive association between adequate tidal volume and visible attempt, with more participants getting in the normal range compared to participants during the hidden attempts (Figure 2). Furthermore, participants had lower proportions in 'Low' and 'High' tidal volumes in the visible groups in comparison to hidden groups.

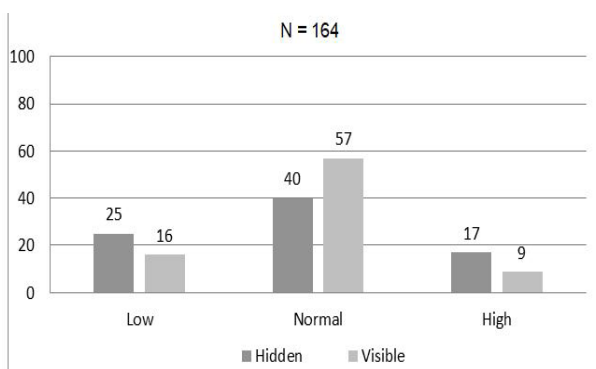


Figure 1. Ventilation attempt by randomization showing normal, low and high range for all ventilation attempts.

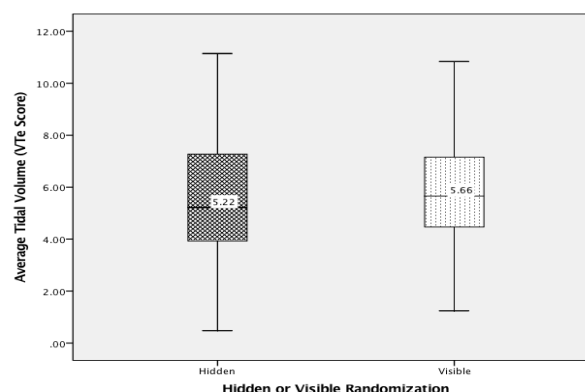


Figure 2. Average tidal volume during ventilation of a neonatal manikin (NeoNatalie) using Laerdal bag and Monivent mask with sensor. Box plots show median values (solid bar), interquartile range (margins of box) and 95% confidence interval.

Participants performed ventilation better when they were shown a ventilation function monitor. While most of the ventilations were within the normal range (4-8 ml/kg), the scores were higher when a monitor was used with scores lower for both low and high ventilation range (Figure 1).

With the visible monitor the average tidal volume during ventilation of a neonatal manikin was higher. Participants were asked to ventilate the manikin on two occasions, once with a monitor and once without a monitor. Box plots showed median values (solid bar), interquartile range (margins of box) and 95% confidence interval (Figure 2).

When asked about confidence regarding providing adequate tidal volume to the newborn, more than 80% of the participants agreed to feeling confident about it (Figure 3).

When asked about whether they are confident about ventilating at 40-60 breathes per minute, more than one third strongly agreed they can do so within the normal range, with more than 80% saying they can ventilate within the normal range (Figure 3).

Regarding adequacy of pressure, more than half of the participants agreed that they can adequately do so while almost one-third were very confident about it (Figure 3).

Less than half of the participants also agreed, they can seal the mask properly to ensure they have given adequate amount of pressure while applying bag and mask with a little less than one-third claiming they can correctly and adequately provide the right amount of pressure (Figure 3).

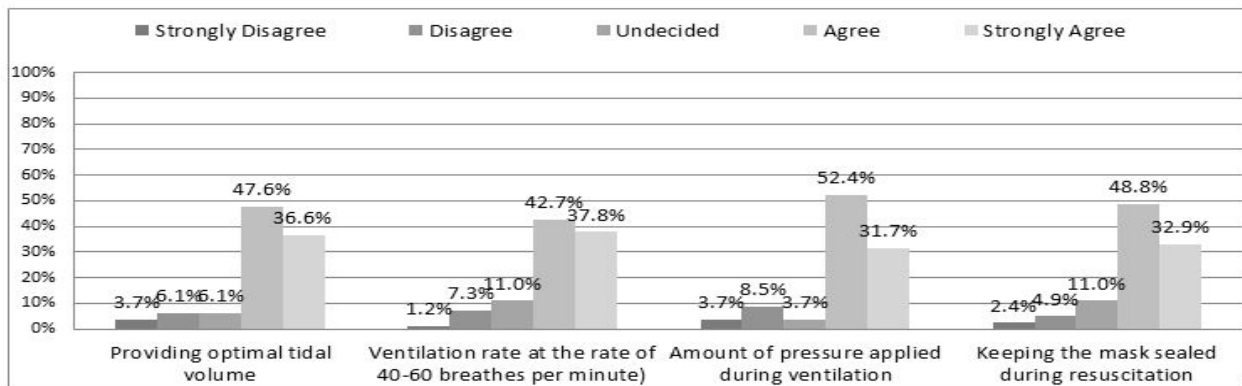


Figure 3. Confidence in neonatal resuscitation following MoniventNeo training (N=82).

When asked regarding their confidence in performing resuscitation in real newborns, almost all the participants mentioned they were confident they can perform bag and mask ventilation properly with more than half agreeing (54.9%) and more than two-fifth strongly agreeing (41.5%) that they can resuscitate a real newborn (Figure 3).

The participants were asked to ventilate the manikin using the device which was either shown or hidden. After the assessment, the participants were asked to share their experiences with the device and if it actually improved their ventilation skills. Not a scientific question. Health workers who were more involved in resuscitation (labor room and operation theatre), they were positive about the device being helpful in improving resuscitation skills of the health workers.

Table 1. Background characteristics of the Health workers.

Background Characteristics	Mean ± SD	Median (IQR)
Age in complete years	33.51±9.55	30.00
Professional experience in midwifery in complete years	12.84±16.16	8.25
Number of deliveries attended per month	6.98±21.03	1.00
Number of resuscitations	2.29±1.36	2.00
Academic Qualifications	Frequency N=82 (%)	
Axillary nurse midwives/ intermediate in nursing	41 (50%)	
Bachelor or master in nursing	23 (28.1%)	
Medical doctor	9 (11.0%)	
Paramedics	9 (11.0%)	

Table 2. Changes in knowledge and skills for preparation for resuscitation, completion of bag-and-mask skill checks, and OSCEs before, immediately after HBB training.

	Before the training (N=82)	Immediately after training (N=82)	p-value
Knowledge (out of 17)	13.96±3.41	15.18±4.12	
Preparation for resuscitation before every birth (out of 5)	1.74±0.44	NA	
Bag and Mask (out of 7)	5.54±2.55	NA	
OSCE A (out of 13)	NA	NA	
OSCE B (out of 18)	15.98±4.04	15.16±2.04	

Table 3. Tidal volume, PEEP and airway leakage with and without monitoring during ventilation.

	With ventilation monitor (N=82)	Without ventilation monitor (N=82)	p-value
Average tidal volume (VT _e)	1.91±0.55	1.90±0.71	0.025
Face mask leakage	64.89±18.72	61.74±18.24	0.235
PEEP	0.18±0.06	0.26±2.46	1.00 (Fisher's exact)

DISCUSSION

The participants performed better ventilations when ventilation function monitor was shown to them in comparison to when it was hidden with most of the ventilations within the normal range. The monitor allowed participants to improve ventilation while performing on the manikin. Our analysis showed there was a significant difference need to show the statistical analysis behind this statement in the results section in visible versus hidden groups in regard to ventilating a manikin. However, a similar type of study showed no marked differences even though the participants agreed that a monitor was indeed helpful.¹¹ Studies have also suggested that optimal tidal volume can be achieved with use of a monitor⁹ and also identify and address any issues.¹⁷ Sufficient ventilation is key to effective neonatal resuscitation, studies have shown.^{18,19} This is due to mask ventilation being challenging and requires years of experience and proper technique.¹⁸ Thus, use of a monitor has its advantages in ensuring ventilation techniques, decreasing mask leakage and measuring tidal volumes.¹⁸ Our analysis corroborates the findings.

Another study has suggested that it is even more important to use a monitor where self-inflating bags are being used. Due to the variability in the amount of pressure given, it can either lead to lower or excess pressure.²⁰ We also noticed that despite using a ventilation function monitor, the participants not always saw the monitor. A study showed similar findings where they suggested that resuscitators barely saw the monitors or if they actually interpreted the data to improve the ventilation.⁸ However, ventilation function monitors should be used to allow resuscitators to control excess Peak Inspiratory Pressure (PIP) and tidal volume.⁷ It is suggested that future trials should consider both initiatives for both simulated and clinical settings.⁷

We had certain limitations in this study. Although randomization was done, this was a manikin study and hence lacks the emotional factors of a real newborn. Furthermore, since the ventilation was done in a quiet room and in a stable condition, the results could be different for a real newborn. However, we used OSCE to simulate what it would be like to ventilate a newborn who does not breathe or cry at birth.

CONCLUSIONS

The ventilation function monitor provides real time feedback showing the amount of pressure. This device will allow health workers to improve their ventilation skills and also ensure that the newborns receive optimal

tidal volume during the ventilation. With a monitor attached to the ventilation equipment, the health workers can perform better and ensure improved survival of newborns.

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