Innovative Journal of Medical and Health Science

IJMHS 9 (9), 608–613 (2019) ISSN (O) 2277:4939 | (P) 2589:9341

EFFICACY OF A NOVEL DEVICE TO DETECT, ALERT AND RESOLVE NEONATAL APNEA - PILOT STUDY

Dr. Swapna Lingaldinna[1], Dr. Himabindu Singh[2], Mona Sharma[3]*

[1]*Niloufer Hospital for Women and Children, Hyderabad, Telangana*

[2]*Niloufer Hospital for Women and Children, Hyderabad, Telangana*

[3]*Bempu Health, Bangalore, Karnataka*

DOI: https://doi.org/10.15520/ijmhs.v9i9.2644

ABSTRACT

Objective: To measure the accuracy of a novel device in detecting Bradycardia and Desaturation (B&D) events and to determine its efficacy in resolving apneas in newborns with comparison to standard monitor (which only detects B&D events and alerts).

Design: This was a prospective observational study.

Setting: Sick Newborn Care Unit of a large tertiary referral hospital in Hyderabad, India.

Methods: 31 newborns were provided with a novel device, which monitored oxygen saturation and pulse rate and alarmed when values dropped below a set threshold which is referred as an event, henceforth. The novel device also provided foot stimulation in response to above-mentioned events. When the monitor alarmed, a nurse attended to the baby to confirm whether the baby was breathing and whether the event had been resolved by the device. If the event had not resolved, appropriate action as per the standard-of-care was performed.

Results: The novel device "ApneBootTM" positively detected B&D events 94.03% of times as compared to the standard reference monitor. 56 of 67 observed B&D events were visually confirmed to be apneas, indicating that 83.6% of B&D events coincided with apneas. Of the 56 apneic events, 50 were central apneas, of which 35 were resolved by the novel device, making the device's efficacy of apnea resolution 70%.

Conclusion: The results of the study indicate that this novel device "ApneBootTM" is very effective in detecting and alarming B&D events, which coincides with the apnea, and resolving it by providing foot stimulation.

* Corresponding author.

† Email: mona@bempu.com.

Keywords: Novel Device, Neonatal Apnea, Low Birth Weight, Body Temperature, Kangaroo Mother Care, Community Health,

INTRODUCTION:

Apnea of Prematurity (AOP) is cessation of breathing that lasts for more than 20 seconds or is associated with desaturation and/or bradycardia for an infant born under 37 weeks gestational age. [1]

Majority of the apneas in premature newborns are AOP which are central in origin. AOP is a serious risk factor for premature newborns [2], and its incidence is inversely correlated with a newborn's gestational age. Nearly all infants born

at <29 weeks gestation or <1,000 g, 54% at 30 to 31 weeks, 15% at 32 to 33 weeks and 7% at 34 to 35 weeks gestation exhibit apnea [3]. If unresolved immediately, prolonged apneas are associated with hypoxia, and bradycardia, which can contribute to hypoxic-ischemic injury of the immature brain [4]. Long-term consequences can include neurodevelopmental impairments and cerebral dysfunction [5-7]. A higher frequency and severity of AOP has been associated with a higher incidence of unfavorable outcomes or death [8].

The burden of AOP is large. In India alone there are 3.3 million premature newborns born each year, a staggering share of the 15 million premature newborns globally who are at risk for apneas annually [9].

Apnea requires immediate intervention, which is possible in neonatal care establishments which have adequate patient nurse ratio and matching numbers of monitors. In these places, there is clinical staff readily available to intervene. [10]. However, in low resource settings, neonatal care units are overloaded and under-resourced. Approximately 55% of Indian Sick Newborn Care Units have inadequate nursing staff [11]. If newborns in such facilities have apneic events, they may be missed or addressed too late due to above mentioned resource constrains. There is a need for a low-cost intervention that not only detects B&D events but also alerts and resolves these events including apneas. The novel device "ApneBoot^{TM}" fulfills all these requirements.

ApneBoot (Figure 1) is a wearable device that detects and alerts for bradycardia and desaturation events, key features of neonatal apnea. ApneBoot resolves central apneas and prevents prolonged hypoxic episodes in premature newborns through an instantaneous tactile stimulation to the sole of the foot. The device has a built-in pulse oximeter with an alarm and an auto-stimulation mechanism that fits on the newborn's foot in a convenient boot form. The parameters used by the ApneBoot to provide the stimulation and alarm are any of the following three conditions, 1) if SpO_2 <85% AND Pulse Rate<100 bpm for continuous 5 seconds, or 2) if SpO_2 <75% for continuous 5 seconds or 3) if Pulse Rate<90 bpm for continuous 5 seconds. This exists as an algorithm in the ApneBoot.

Figure 1: ApneBoot device

If an event occurs, ApneBoot provides a vibro-tactile stimulation to the newborn's sole of the foot, stimulating them to restart breathing. It simultaneously also emits an audiovisual alarm to get a caretaker's attention in case the event requires additional intervention. The device can be worn immediately upon birth and fits all premature newborns.

AIMS:

The aim of the study was to determine the accuracy of the device in detecting B&D events as compared to a standard monitor, and its efficacy in resolving the associated apneas.

The timely resolution of apneas will improve the pulse rate and oxygen saturation in these newborns saving them from associated injury and complications.

MATERIALS AND METHODS:

This study was conducted from August 2018 to November 2018 in the Sick Newborn Care Unit at Niloufer Hospital, Hyderabad, India. Institutional Ethics Committee permission was obtained. Preterm newborns of less than 34 weeks of gestation and less than one month of age were enrolled in the study with written parental consent. Further the newborns that were on low flow oxygen and caffeine and were not receiving any supportive ventilation were included in the study. However, newborns that had congenital lethal abnormalities or any significant cardiac abnormalities were excluded. The demographic profile of the enrolled newborns is described in Table 1. Subjects were enrolled until they were no longer eligible as per the eligibility criteria or were discharged due to any cause.

Enrolled newborns wore an ApneBoot device and were also connected to a standard monitor for comparison of ApneBoot's accuracy in detecting bradycardia and desaturation.

The ApneBoot device uses a standard pulse oximeter OEM III module manufactured by Nonin® with reusable flex sensors for neonatal applications, with SpO2 accuracy of ±3 digits (70-100%) and ± 4 digits (for motion and low perfusion), pulse rate accuracy of ±3 digits (18-300 bpm) and ± 5 digits (for 40-240 bpm with motion, low perfusion). The Schiller Truscope II Patient Monitor was used as the standard monitor for comparison with SpO2 accuracy of ± 2% (70-100%) and unspecified for (0-69%), pulse rate accuracy of ± 1% or ±1 bpm whichever is greater.

A nurse attended to the baby when the alarms sounded and visually confirmed whether the baby was breathing. If the ApneBoot had not resolved the apnea, appropriate measures meeting the standard of care were taken; the study coordinator recorded the following

- Number of times the alarms were heard,
- The measured value of the pulse rate and oxygen saturation on both the devices
- Noted the breathing status; whether breathing or not
- Number of times the nurse intervened and whether they had to provide foot flicking and any other intervention

Whenever possible the newborns were monitored by a video camera.

Data was analyzed using Microsoft Excel Version 10 to determine ApneBoot's Positive Predictive Value, indicating its accuracy at detecting true bradycardia and desaturation (B&D) events as compared to a standard monitor, and to calculate the relationship between these B&D events and apneas, and the efficacy of the device's stimulation, indicating its success in resolving apneas.

The newborns were monitored for any signs of physical harm such as rashes, burns, or abrasion due to the stimulation.

RESULTS:

31 newborns in the study were monitored for 47 days for a total of 313 hours. ApneBoot alarms (indicating B&D events) were compared with corresponding values indicated by the standard monitor.

Table 1. Demographic characteristics of newborns enrolled in the study.

GA Group	N	Days of monitoring	Male	Female	Mean birth weight +/- SD (grams)	Mean GA +/- SD (weeks)
<29 weeks	4	8	1	3	828	28
29-32 weeks	14	22	6	8	1226	31.4
33+ weeks	13	17	4	9	1345	33.5
Total	31	47	11	20	1224 +/- 295	31.8 +/- 1.9

67 B&D events were observed in the enrolled newborns. Out of these, 56 events were visually confirmed to be apneas (cessation of breathing was seen by the study coordinator).

Of the 56 apneic events 50 were determined through visual observation by the study coordinator to be central apneas (apneas capable of being resolved by a tactile stimulation) and were confirmed with the results of a video recording.

Table 2. Study findings

GA Group	Number of ApneBoot alarms (i.e. B&D events)	Number of times standard pulse oximeter confirmed B&D events (true positives)	Number of times standard pulse oximeter did not confirm B&D events (false positives)	Positive Predictive Value (PPV%)	False alarm rate (%)
<29 weeks	23	20	3	86.9	13.0
29-32 weeks	12	12	0	100	0
33+ weeks	32	31	1	96.8	3.1
Total	67	63	4	94.03	5.97

Results demonstrated that ApneBoot positively detected a B&D event 94.03% of times (i.e., ApneBoot has a 94.03% Positive Predictive Value), as compared to the standard monitor (results displayed in Table 2). With the figures of observer and video recording values mentioned above 83.6% of B&D events (56/67) coincided with apneas and were accurately detected as apneas by ApneBoot.

Of the 50 central apnea events, ApneBoot stimulation resolved 35 events and no nurse intervention was required. Thus in this study, ApneBoot's efficacy of auto-resolving apneas was 70% (35/50). Additional details on the apneas experienced by the subjects are described in Table 3.

Table 3. Efficacy in auto-resolving apneas

Total number of days of monitoring [number of newborns monitored]	47 [31]
Total number of apneas detected	56
Number of apneas requiring bag and mask or oxygen support (i.e. apneas not capable of being resolved by tactile stimulation)	6
Number of apneas capable of being resolved by a tactile stimulation (=56-6)	50
Number of apneas resolved by ApneBoot	35
Number of apneas requiring nurse intervention (flicking of foot sole)	15
Efficacy of ApneBoot in auto-resolving apneas (35/50)	**70%**

DISCUSSION:

The results of this study are promising for ApneBoot's potential to detect and resolve bradycardia and desaturation events and associated apneas in settings where human resources for apnea management are limited. ApneBoot's high Positive Predictive Value (PPV) suggests that it is highly accurate at detecting bradycardia and desaturation events. In addition, it has significant advantage of auto stimulation demonstrating its superior utility in the management of newborns as compared to the standard monitors. The high rate of bradycardia and desaturation events coinciding with apneas suggests that ApneBoot's algorithm is suitably designed to detect neonatal apneas.

ApneBoot's high apnea resolution rate (70%) demonstrates that the device has the potential to be an effective intervention to resolve apnea in settings where resources are limited.

No clinical events suggestive of Intra Ventricular Haemorrhage occurred during the study. There was no evidence of skin injury from the stimulation in enrolled newborns. Hence, ApneBoot was found to be safe for use in newborns.

This was an observational pilot study and was conducted on a small number of newborns. A more robust large controlled trial is required to further explore ApneBoot's potentials in the management of apnea.

CONCLUSION:

ApneBoot is very accurate at detecting bradycardia and desaturation events as compared to a standard monitor. A large majority of these events coincided with apneas in newborns. ApneBoot is able to resolve apneas at a high rate, demonstrating its potential for utility for apnea management in settings that are under-resourced.

REFERENCES:

1. American Academy of Pediatrics, Committee on Fetus and Newborn. Apnea, sudden infant death syndrome, and home monitoring. Pediatrics. 2003 Apr. 111(4 Pt 1):914-7.
2. Chandrasekharan P, Rawat M, Reynolds AM, Phillips K, Lakshminrusimha S. Apnea, Bradycardia and Desaturation Spells in Premature Infants – Impact of a Protocol for Duration of "Spell-Free" Observation on Inter-Provider Variability and Readmission Rates. Journal of Perinatology. 2017;38(1):86-91. doi:10.1038/jp.2017.174.
3. Martin RJ, Abu Shaweesh JM, Baird TM (2004) Apnoea of prematurity. Paediatr Respir Rev 5(Suppl 1):S377–S382
4. Robertson CM, Watt MJ, Dinu IA (2009) Outcomes for the extremely premature infant: what is new? And where are we going? Pediatr Neurol 40(3):189–196
5. Pilcher G, Urlesberger B, Muller W (2003) Impact of bradycardia on cerebral oxygenation and cerebral blood volume during apnoea in preterm infants. Physiol Meas 24(3):671–680
6. Janvier A, Khairy M, Kokkotis A et al (2004) Apnea is associated with neurodevelopmenta impairment in very low birth weight infants. J Perinatol 24(12):763–768
7. Zhao J, Gonzalez F, Mu D (2011) Apnea of prematurity: from cause to treatment. Eur J Pediatr 170:1097-1105
8. Pillekamp F, Hermann C, Keller T et al (2007) Factors influencing apnea and bradycardia of prematurity-implications for neurodevelopment. Neonatology 91(3):155–161
9. Blencowe H, Cousens S, Oestergaard M, Chou D, Moller AB, Narwal R, Adler A, Garcia CV, Rohde S, Say L, Lawn JE. National, regional and worldwide estimates of preterm birth. The Lancet, June 2012. 9;379(9832):2162-72. Estimates from 2010.
10. Rogowski JA, Staiger DO, Patrick TE, Horbar JD, Kenny MJ, Lake ET. Nurse Staffing in Neonatal Intensive Care Units in the United States. Research in Nursing & Health. 2015;38(5):333-341. doi:10.1002/nur.21674.
11. Care of Small and Sick Newborns in Special Newborn Care Units (SNCUs) of India. Ministry of Health & Family Welfare, Government of India; 2015.).

AUTHOR BIOGRAPHY

Dr. Swapna Lingaldinna, Niloufer Hospital for Women and Children, Hyderabad, Telangana
Dr. Himabindu Singh, Niloufer Hospital for Women and Children, Hyderabad, Telangana
Mona Sharma, Bempu Health, Bangalore, Karnataka