ORIGINAL RESEARCH

Comparison of two different Nasal Interfaces used in Non-Invasive Respiratory support in terms of Neonate comfort

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Abstract

Background

Non-Invasive Ventilation (NIV) is the first choice approach in neonates with sufficient respiratory effort that require respiratory support. The type of nasal interface used in NIV affects both efficacy and patient comfort. The aim of this study is to investigate the effects of different nasal interfaces used in NIV support on neonatal patient comfort.

Methods

Our study evaluated patients who received NIV support for 24 hours. The patients were randomly divided into two groups according to the type of nasal interface used, which were RAM cannula and short binasal prong (SBP). The patients' demographic and clinical data were noted. Their sleep was monitored for 24 hours with an actigraphy device.

Results

A total of 82 patients were evaluated. The sleep efficiency in the RAM cannula group was significantly higher (respectively, 65.7% [10.22-95.25] vs. 57.81% [2.49-77], p=0.004). Although not statistically significant, the neonates in the RAM cannula group exhibited longer total sleep time (respectively, 10.4 ± 4.28 hours vs. 9.02 ± 3.73 hours, p=0.161). Comparison of heart rates and respiratory rates indicate that the patients in the RAM cannula group were more comfortable.

Conclusions

Our study found that infants who received NIV support through a RAM cannula experienced more efficient sleep. Holistic approaches in neonatal intensive care units are vital for better neurodevelopmental outcomes in newborns. Although non-invasive, the interface used in NIV should also be a part of this holistic approach.

Keywords: Actigraphy, RAM cannula, short binasal prong, sleep, neonate

Introduction

Sleep is a fundamental and necessary requirement in every stage of life. Newborn infants require longer durations of sleep compared to adults. Furthermore, premature infants devote nearly 90% of their day to sleep, with this number decreasing as the weeks of gestation increase[1,2]. The proper establishment of sleep and sleep-wake cycles have been proven to benefit cognitive development in pre-school and school-aged children[3,4]. A decrease in sleep quality negatively affects learning and cognitive performance[5]. Although limited studies have been conducted on sleep in the neonatal period, research suggests that sleep positively effects cognitive and physical development starting from the neonatal period[6].

The intrauterine environment provides the optimal conditions for brain development in infants[7]. Infants are exposed to various environmental factors upon birth. In particular, infants in intensive care units are exposed to several negative factors that can negatively impact sleep quality; this includes invasive procedures, respiratory support, noise and light[8]. The sympathetic nervous system is activated by painful interventions; this can result in an increase in heart rate, blood pressure, and intracranial pressure, as well as a drop in oxygen saturation and a change in breathing pattern. Unfavorable circumstances such a pneumothorax and a cerebral hemorrhage may also ensue[9], [10]. Respiratory support is a vital intervention for infants in intensive care units. Non-invasive respiratory support is frequently used for both initial and post-extubation respiratory support[11]. Non-invasive ventilation support is the preferred approach for infants with sufficient respiratory effort who require respiratory support. The choice of nasal interface in NIV has significant effects on efficacy. In the literature, there is no published research on the relationship between neonates sleep and cannula type, and we believe that nasal interfaces also affect patient comfort due to differing designs. Uncomfortable NIV interfaces lead to less effective outcomes[12]. The majority of studies on non-invasive ventilation are related to efficacy and acute complications[13,14]. In the literature, there is no published research on the relationship between neonates sleep and cannula type. In this study, we investigated which nasal interface type (RAM cannula or SBP) is more comfortable for neonates to sleep with while getting NIV support.

Methodology

This prospecitve longitudinal study was conducted between

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January 2022 and June 2022. The study included infants in the neonatal intensive care unit who received nasal respiratory support for a 24 hour period. Exclusion criteria for infants included; a gestational age ≤26 weeks, those in the first 24 hours of life, major congenital anomalies, diagnosis of asphyxia, and those who received sedative drugs in the 24 hours prior. Infants who were removed from nasal respiratory support or re-intubated before completing 24 hours were also excluded from the study. The patients' demographic (gestational age, birth weight, gender, postnatal day at study inclusion) and clinical (NIV indication, peak heart rate, respiratory rate, and blood pressure) data were noted. The heart rate, respiratory rate, and blood pressure of the infants were monitored at regular intervals, and their arithmetic averages were recorded.

Ethics approval

This study was contucted in the neonatal intensive care unit of Turgut Ozal Medical Center at Inonu University, Faculty of Medicine. Approval from the ethics committee was obtained prior to the study (2021/2730).

Randomization and Blindig

Infants who met the inclusion criteria and required nasal respiratory support were randomized into two groups. As a randomization method, the "Simple Randomization (or Complete Randomization)" method, which is known as the assignment of individuals who meet the criteria for participation in the study, to the groups completely randomly, with equal chance and regardless of the previous assignment, was used[15]. Open-label blinding was used as blinding method[16]. Using sealed envelopes, the patients were distributed into two groups with respect to the type of nasal interface used, the RAM cannula (NeotechTM, Valencia, CA) group and short binasal prong (SBP) (Hudson Respiratory Care Inc, Temecula, CA and easy Flow NCPAP systems, Stephan, Germany or Easy Flow bi-nasal prong Fritz Stephan GmbH Gackenbach, Germany) group.

Non-invasive Ventilation Protocol

In our clinic, nasal respiratory support is the initial approach in infants with sufficient respiratory effort who still require respiratory support. The preferred starting mode is nasal intermittant positive pressure ventilation (NIPPV). The starting NIPPV values are set to; a rate of 20-30/min with 0.4 seconds for inspiration time, 5-8 cmH2O for positive end-expiratory pressure (PEEP), 15-20 cmH2O for peak inspiratory pressure (PIP), and a fraction of inspired oxygen (FiO2) of 0.21-0.50 depending on the target saturation range. While being monitored, adjustments were done based on the patients' clinical condition, lung radiography and blood gas values.

Actigraphy

Actigraphy (ACTIWATCH 2) is a non-invasive sleep-wake accelerometer measurement device that is attached to the wrist/ankle of infants and records long-term sleep and wake states. The weight of the device is 16 grams with the wristband and its dimensions are 43mm x 23mm x 10mm. The device has a stand with a USB connection that allows for charging and data transfer. The actigraphy device contains a 1 Mbit internal memory and operates on Windows 2000, Windows XP, Windows Vista, Windows XP Pro, Windows Vista Business or Vista Ultimate. Movements detected by the device are encoded as sleep or wakefulness through embedded algorithms that utilize reduction in the rate of

Table 1. The demographic, clinical and actigraphy data of patients monitored during non-invasive respiratory support

		RAM cannula (n=41)	Short binasal prong (SBP) (n=41)	p-value
Birth weight, gram		2295(730-4500)	1700(830-3200)	0.137*
Gestational week, week		33(27-40)	31(26-39)	0.122*
Postnatal day, day		3(1-42)	4(1-53)	0.498*
Heart rate /minute		139.83±11	146.8±7.53	0.001**
Respiratory rate /minute		56(43-65)	60(45-64)	0.008*
Systolic blood pressure,mmHg		68.24±6.91	71.1±7.11	0.093**
Diastolic blood pressure,mmHg		39.22±6.17	41.37±6.97	0.100**
Mean arterial pressure, mmHg		48.89±5.72	51.32±6.54	0.039**
Sleep efficiency, %		65.7(10.22-95.25)	57.81(2.49-77)	0.004*
Total sleep time, hour		10,4±4.28	9.02±3.73	0.161**
Gender	Female, n (%)	20 (48.8)	11 (26.8)	0.068***
	Male, n (%)	21 (51.2)	30 (73.2)	
Type of delivery	Vaginal delivery, n (%)	2 (4.9)	2 (4.9)	1.000***
	Cesarean delivery, n (%)	39 (95.1)	39 (95.1)	
NIV indication	RDS, n (%)	19 (46.3)	29 (70.7)	0.052***
	Pnömonia, n (%)	4 (9.8)	4 (9.8)	
	TTN, n (%)	18 (43.9)	8 (19.5)	

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Table 2. Results of logistic regression analysis

	Univariate Analysis				Logistic Regression Analysis			
	OR	95% CI for OR		p-value	AOR	95% CI for AOR		p-value
		Lower	Upper			Lower	Upper	
Mean heart rate	1.083	1.028	1.141	0.003	1.075	1.012	1.142	0.020
Sleep efficiency	0.978	0.956	0.999	0.05	0.968	0.942	0.993	0.014
Gestational week	0.893	0.788	1.013	0.079	0.819	0.670	1.001	0.051
Mean systolic blood pressure	1.061	0.995	1.131	0.072	1.134	1.032	1.247	0.009

sleep-associated movement. The program automatically calculates sleep efficiency using sleep time and number of awakenings. Actigraphy has been previously used to assess sleep patterns in the pediatric age group[17,18]. Its utility in assessing sleep patterns in premature infants has been validated[19,20].

Statistical Analysis

The method used to determine the sample population of the study is the "Systematic Sampling" method. When Type 1 error amount (alpha) was 0.05, test power (1-beta) was 0.95, effect size was 0.81 (large), and alternative hypothesis (H1) was two-sided, the required minimum sample size for find a statistically significant difference between the RAM cannula and Short binaural prong (SBP) groups. There should be 82 individuals, 41 in each group. G.Power 3.1.9.2 was used to calculate the sample size[21]. Data were expressed as mean ± standard deviation and median (min-max). The Kolmogorov-Smirnov test was used to assess normal distribution of data. The statistical analyses were conducted using the Mann-Whitney U test, Pearson Chi-Squared test, Yates Corrected Chi-Squared test and Fisher's Exact test where suitable. The program used for analyses was IBM SPSS Statistics 22.0 software. Logistic regression was used to evaluate odds ratios. A p-value of <0.05 was considered statistically significant.

Results

A total of 95 patients were initially included in the study, with 7 patients being re-intubated in the first 24 hours and 6 being removed from NIV support prior to completing 24 hours; these patients were excluded, therefore, the study was conducted with 82 patients. The patients were randomized into two groups consisting of the RAM cannula and SBP groups. Both groups exhibited similar demographic characteristics. In comparison to the SBP group, the RAM cannula group displayed statistically lower values pertaining to mean heart rate (respectively, 146.8 ± 7.53/min vs. 139.83 ± 11/min, p=0.001), median respiratory rate (respectively, 60/min [45-64] vs. 56/min [43-65], p=0.008), and MAP (respectively, 51.32 ± 6.54 mmHg vs. 48.89 ± 5.72 mmHg, p=0.039).

According to the results of actigraphy evaluation, the mean sleep efficiency was significantly higher in the RAM cannula group compared to the SBP group (respectively, 65.7% [10.22 - 95.25] vs. 57.81% [2.49-77], p=0.004). The total sleep duration in the RAM cannula group, although not statistically significant, was also found to be longer (respectively, 10.4 ± 4.28 hours vs. 9.02 ± 3.73 hours, p=0.161) (Table 1).

According to the logistic regression analysis; the SBP group was 1.075 times higher than the RAM cannula group for each unit increase in mean peak heart rate; sleep efficiency was 1.03 times higher in the RAM cannula group as opposed to the SBP group; and mean systolic blood pressure was 1.134 times higher in the SBP group when compared to the RAM cannula group (Table 2).

Discussion

We found that babies who were supported with non-invasive ventilation with a RAM cannula sleeping more efficiently than those who were ventilated non-invasive with an SBP, and that a RAM cannula was also more comfortable for the infant. To this day, research on RAM cannula has mainly focused on its effectiveness[13,14]. In a study, Samim et al. found that the RAM cannula is similar to short binasal prongs in effectively providing nasal respiratory support[22]. Successful NIV support protects neonates from intubation and its many associated complications[11]. Ensuring patient comfort in those receiving NIV increases the success rate of the procedure. The type of nasal interface used is among the factors affecting patient comfort. The efficacy of treatment may vary depending on interface design[12]. Due to the thin and long design of the RAM cannula, there is resistance against the applied pressure; therefore, higher pressures are required to deliver sufficient air to the lungs[23]. In their study, Claasen et al. emphasized the importance of higher PEEP pressure for effective treatment through RAM canulae[13]. RAM cannulae also provide ease of use. The convenient fixation of a RAM cannula provides comfort for both neonates and caregivers. Studies have found that the RAM cannula causes fewer nasal injuries; secondary outcomes such as these support the RAM cannula as a more comfortable interface[14,22]. Uncomfortable infants may have increased heart rate and breathing rate due to increased sympathetic activation[9,10]. In our study, the low values of heart rate and respiratory rate of patients monitored with a RAM cannula support that the RAM cannula is a more comfortable interface.

Actigraphy is a non-invasive method measuring motion and sleep duration. In a study involving 40 neonatal infants, Unno et al. utilized both polysomnography and actigraphy and showed that actigraphy is reliable for assessing sleep in infants[20]. In their study on neonates, Sheellhaas et al. found that inefficient and inadequate sleep is associated with low delta activity on EEG and is predictive of poor long-term outcomes[24]. Painful interventions in the neonatal period may have negative effects on patients in the long term as well as acute effects. Sleep disorders can negatively impact many prospects of health, including neurological development and overall growth, particularly in the early stages of life[25]. Proper development of sleep and sleep-wake cycles during the early periods of life positively affects neurodevelopment in infants. Contemporary data suggests that infants with poor sleep quality carry risk for impaired neurocognitive outcomes[26]. Neonatal infants require comprehensive holistic approaches for proper neurodevelopmental progress. During this comprehensive approach, clinicians should be mindful that, although non-invasive, NIV support may affect infant comfort and sleep quality. The limitation of our study is the lack of long-term outcomes of the patients. In addition,

our study is valuable because it is the first study to examine the relationship between sleep and nasal interface type in newborns using actigraphy.

Conclusion

Nasal interfaces affect the comfort of the patient, even though they are non-invasive procedures. Our study supports that the RAM cannula is a more comfortable interface in newborns than short binasal prognoses. Comfortable NIV support is beneficial for both long-term neurodevelopment and NIV efficacy. There is need for future studies examining sleep profiles and long-term neurodevelopmental outcomes in neonates receiving non-invasive support.

Declarations

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Conflicts of interest/ Competing interests

The authors declare that they have no conflict of interest.

Availability of data and material

The data sets used and/or analyzed during the current study are available from the corresponding author on reasonable request.

Authors' contributions

MFD, YSD, EHY, RO participated in the study design. MFD, YSD, MA collected data. MFD, SY analyzed data and interpreted results. MFD, IKG, EHY, RO interpreted results and edited the manuscript. All authors read and approved the final manuscript.

Ethical approval

The study was approved by Inonu University Institutional Ethics Committee. (2021/2730)

Consent for publication

The manuscript is approved by all authors for publication.

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