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A Comparative Study between Postextubation of Preterm Neonates into High-Flow Nasal Cannula versus Nasal Continuous Positive Airway Pressure

Ramy Saleh Morsy[1*], Magda Mahmooud Sedky Badawy[2], Reem Nabil Said[2], Aliaa Adel Ali[2], Walaa Alsharany Abuelhamd[2]

1. Armed Forces College Of Medicine, Egypt
2. Faculty of Medicine, Cairo University, Egypt

ABSTRACT

Background: For respiratory support in premature newborns, there has been a trend toward less tracheal intubation, less mechanical ventilation, and more nasal respiratory support which can result in the improvement of successful extubation rate. The two commonly known types of nasal respiratory support after extubation are the nasal continuous positive airway pressure (CPAP) and high flow nasal cannula (HFNC). The current study aimed to investigate and compare successful extubation using HFNC and conventional nasal CPAP after a period of endotracheal positive pressure ventilation and detect which of these two methods is better for successful extubation with fewer side effects.

Methods: This randomized controlled study was conducted on 210 preterm newborns in the neonatal intensive care unit (NICU) of Gynecology and Obstetrics Department of Qasr El Eyni Hospital. Post extubation failure rates were compared between the two groups, namely (HFNC) and (nasal CPAP). The collected data were analyzed in SPSS software (version 20).

Results: Neonates who needed re-intubation within 72 h after initial extubation were higher in the HFNC group (72.7%) versus (27.3%) in the CPAP group (P-value=0.063). Moreover, 45.8% of neonates in the HFNC group needed re-intubation within 1 week of initial extubation versus 54.2% in CPAP (P-value=0.970). The mean duration of respiratory support using HFNC was 3.7 days, compared to 6.5 days using CPAP (P-value= 0.001). Among neonates who suffered from nasal trauma, 90.6% of neonates belonged to the CPAP group, while 9.4% of cases belonged to the HFNC group (P-value= 0.001).

Conclusion: The use of CPAP and HFNC after the extubation of preterm mechanically ventilated neonates was statistically equal regarding extubation failure.

Keywords: CPAP, Extubation failure, HFNC, Preterm

Introduction

Neonatal respiratory disorders account for the majority of admissions to neonatal intensive care units (NICUs). Initial stabilization of the neonate through the management of the airway, breathing, and circulation takes precedence over determining the cause (1). In this regard, a new trend has emerged to use a lower level of ventilation and a higher level of respiratory support in case of supporting premature neonates' breathing. The most popular and primary mode of respiratory support in neonates is using different methods of supporting nasal respiration since its application is linked to decreasing the need for mechanical ventilation and the related lung injury (2).

The two commonly known types of nasal respiratory support after extubation are the nasal continuous positive airway pressure (CPAP) and high flow nasal cannula (HFNC). The current study aimed to investigate and compare successful

* *Corresponding author*: Ramy Saleh Morsy, Armed Forces College Of Medicine, Egypt. Tel: +2001007211375; Email: ramy.saleh1983@yahoo.com

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extubation using HFNC and conventional nasal CPAP after a period of endotracheal positive pressure ventilation.

The current study aimed to investigate and compare successful extubation using HFNC and conventional nasal CPAP after a period of endotracheal positive pressure ventilation and detect which of these two methods is better for successful extubation with fewer side effects.

Methods

Design and patients

This randomized controlled study was conducted on 193 neonates in the neonatal intensive care unit of Obstetrics and Gynecology Hospital of Cairo University over a period of 30 months from 7/2015 to 12/2017. The neonates were randomized using sequentially numbered, opaque sealed envelopes (SNOSE) method into HFNC (n=88) and nasal CPAP (n=105) groups to compare extubation failure between the two groups during first 72 h and 1st week after extubation.

Inclusion criteria

In the current study, eligible neonates were born at a gestational age of 28-34 weeks. They received mechanical ventilation through an endotracheal tube. In addition, the clinical team scheduled them for undergoing extubation for the first time for noninvasive respiratory support, which was formed by nasal CPAP or HFNC.

Exclusion Criteria

- Full-term neonates or large for gestational age
- Preterm neonates not supported primarily by invasive ventilation
- Newborns with major cardiopulmonary malformations, congenital airway malformations, or suspected upper airway obstruction

Randomization, intervention, and data collection

After obtaining parents' consent, preterm mechanically ventilated newborns were randomized using sequentially numbered, opaque sealed envelopes (SNOSE) method into HFNC (n=88) and nasal CPAP (n=105) groups. The primary outcome, extubation failure, was categorized by specified failure criteria in the first 72 h and 7 days after extubation. Sealed envelope method was used for randomization, rather than online software applications, since the decision and timing of extubation was at the discretion of the treating physician in charge at extubation time and the sealed opaque envelopes that were opened immediately before extubation

Individual failure criteria of extubation

- Apnea (respiratory pause >20 seconds), more than 6 episodes in 6 h or 1 requiring intermittent positive pressure ventilation.
- Acidosis, pH <7.25 and PCO_2 >65 mmHg
- More than 15% continuous increase in FiO_2 from the baseline of extubation required for maintaining a peripheral saturation of oxygen of 88-92%
- Increased effort of respiratory
- The failure of extubation was taken into account when any single criterion was satisfied on any of the post-extubation in 7 days. The treating team was responsible for deciding whether to reintubate a newborn.

In the present study, all neonates were subjected to

1. Careful history taking
2. Full clinical examination
3. Investigations, including:

- Complete blood picture with differential white cell count
- C-reactive protein (CRP)
- Blood culture on suspicion of neonatal sepsis
- Arterial blood gases
- Radiological examination (chest X-ray).
- Cranial ultrasound with a clinical suspicion of intracranial hemorrhage and its grade.
- Echocardiography whenever congenital heart disease is suspected

In the current study, eligible neonates were born at a gestational age of 28-34 weeks. They received mechanical ventilation through an endotracheal tube. In addition, the clinical team scheduled them for undergoing extubation for the first time for noninvasive respiratory support. In the post-extubation of preterm neonates < 34 weeks, a comparison was made between the two groups: HFNC and nasal CPAP. The neonates were maintained on their assigned mode of respiratory support until they were able to manage without respiratory support.

When a neonate showed one of the signs of individual failure criteria of extubation, he/she was changed immediately into a higher option of respiratory support keeping re-intubation decisions with the treating team.

Statistical analysis

Data were statistically described in terms of mean±standard deviation (± SD), median and range, frequencies (number of cases), and percentages when appropriate. The numerical variables between the study groups were compared using Student's t-test for independent samples; in addition, Chi-square ($\chi 2$) test was conducted to compare the categorical data. However, when the expected frequency was less than 5, Fisher's exact test was used instead. A P-value less than 0.05 was considered statistically significant. Quantitative data were presented as mean and standard deviation (SD). The data were explored for normality by checking the data distribution and using Kolmogorov-Smirnov and Shapiro-Wilk tests.

For parametric data, Student’s t-test was used to compare the two groups. On the other hand, for non-parametric data, the Mann-Whitney U test was used to compare the two groups. Logistic regression analysis was performed to study the effect of different variables on extubation failure. By using logistic stepwise multi-regression analysis, we can get the most sensitive ones that predict the dependent variable according to their P-values. All statistical calculations were performed in IBM SPSS software (Statistical Package for the Social Science; IBM Corp, Armonk, NY, USA) (version 22)for Microsoft Windows.

Sample size calculation was performed by comparing the incidence of extubation failure between cases treated with HFNC and those treated with nasal CPAP among preterm neonates in the immediate post-extubation period. The calculation was conducted based on comparing two proportions from independent samples in a prospective study using the chi-square test, the α-error level was fixed at 0.05, the power was set at 80%, and the intervention groups (case: control) ratio was set at 1. Sample size calculation was performed using PS Power and Sample Size Calculations software (version 3.0.11) for MS Windows (William D. DuPont and Walton D. Vanderbilt, USA).

Results

There was no statistically significant difference in the demographic data between CPAP and HFNC groups (P-value > 0.05). Nonetheless, a statistically significant difference was observed in three of the ventilation variables between CPAP and HFNC groups. Moreover, there was a statistically significant difference in the number of days spent on CPAP (6.50±3.821 days), compared to the number of days on HFNC (3.74±1.980 days) (P=<0.001). The age for starting non-invasive

Table 1. Comparison of demographic data and clinical characteristics between the two study groups

Parameters		CPAP	HFNC	P-value
		n=105	n=88	
Gender	Female Male	50 (50.0%) 55 (59.1%)	50 (50.0%) 38 (40.9%)	0.203
Birth Weight (gm)	Mean±SD Range	1.578 ± 0.978 0.800 – 1.775	1.609± 0.3837 0.900- 2.500	0.352
Gestational Age (wks)	Mean±SD Range	32.15 ± 1.651 28 – 34	32.27±1.880 28-34	0.636
Prenatal Steroids	No Yes	61(52.6%) 44 (57.1%)	55 (47.4%) 33 (42.9%)	0.534
Delivery Mode	Cesarean Normal	78 (55.7%) 27 (50.9%)	62 (44.3%) 26 (49.1%)	0.553
Chorioamnionitis	No Yes	99 (53.8%) 6 (66.7%)	85 (46.2%) 3 (33.3%)	0.449
Surfactant Use	No Yes	70 (58.3%) 35 (47.9%)	50 (41.7%) 38 (52.1%)	0.160
Late onset Sepsis	No Yes	45 (51.1%) 60 (57.1%)	43 (48.9%) 45 (42.9%)	0.404
APGAR 1	Mean±SD Range	4.53 ± 1.193 3-8	4.59±1.219 2-7	0.741
APGAR 5	Mean±SD Range	7.30±0.865 5-10	7.42 ± 0.931 5-9	0.335
Down Score	Mean±SD Range	5.55±0.820 4-7	5.69±0.793 4-7	0.229

*: Significant at P < 0.05
CPAP: Continuous positive airway pressure
HFNC: High flow nasal cannula

support differed significantly between patients extubated to CPAP and those extubated to HHFN (6.20±5.066 days versus 11.77±7.827 days, respectively), (P<0.001). The oxygen saturation at the time of extubation was statistically significantly higher in the patients extubated to HFNC (93.14± 2.600 %), compared to those extubated to CPAP (92.45± 2.062 %)(P=0.046) (Table 2).

A number of 29 patients who were extubated to CPAP experienced extubation failure (3 cases within first 72 h and 26 subjects within the first week after extubation), compared to 30 patients who were extubated to HFNC (8 cases within first 72 h and 22 within the first week after extubation), a difference which was not statistically significant (P=0.970). The only statistically significant difference between CPAP and HFNC groups regarding extubation failure was the age in which re-intubation occurred which was higher in the HFNC group, compared to that in the CPAP group (Table 3).

There was no statistically significant difference between causes of extubation failure in the two groups, except for the incidence of severe persistent retraction which was statistically significantly higher in the CPAP group, compared to the HFNC group. Nevertheless, a statistically significant difference was detected between the prevalence of three complications in the two groups. Incidence of nasal trauma and intraventricular hemorrhage (all grades) were statistically significantly higher in the CPAP group, compared to that in the HFNC group. However, when comparing the incidence of grade III or IV intraventricular hemorrhage between both groups, no statistically significant difference (P=0.549) was observed. On the other hand, the

Table 2. Comparison of ventilation data between the two groups

		CPAP n=105	HFNC n=88	P-value
Peak Inspiratory Pressure at extubation time (CmH_2O)	Mean±SD Range	13.48±1.256 10-15	13.55±1.372 11-15	0.715
PEEP at extubation time (CmH_2O)	Mean±SD Range	4.63 ± 0.84 4-6	4.67± 0.582 4-6	0.628
Ventilation Rate at extubation time (B/min)	Mean±SD Range	33.48± 4.500 25- 45	32.33± 5.139 20-40	0.100
Fio2 at extubation time	Mean±SD Range	35.62± 7.295 25- 50	35.74± 5.700 25-50	0.901
Duration of Mechanical Ventilation (hours)	Mean±SD Range	108.80± 91.211 24-360	173.18± 131.073 48-480	0.435
Days on CPAP V.S Days on HFNC	Mean±SD Range	6.50± 3.821 1-16	3.74± 1.980 1-9	<0.001*
Start Age of noninvasive support (in days)	Mean±SD Range	6.20± 5.066 2-22	11.77± 7.827 3- 36	<0.001*
Oxygen saturation at extubation time	Mean±SD Range	92.45± 2.062 88- 98	93.14± 2.600 90- 98	0.046*
Total duration of oxygen therapy (days)	Mean±SD Range	20.85± 14.470 5-60	19.15± 12.172 6-60	0.376

* Significant at P< 0.05
CPAP: Continuous positive airway pressure
HFNC: High flow nasal cannula

Table 3. Comparison of extubation failure between the two groups

		CPAP		HFNC		P-value	95%CI of risk dif.		
		No.	%	No.	%		Range	Upper	Lower
Failed extubation	During 72 hours	3	27.3%	8	72.7%	0.063	6.80	0.57	-13.03
Failed extubation	During week	26	54.2%	22	45.8%	0.970	9.10	-13.43	-31.62
Re intubation	Total	29	49.2%	30	50.8%	0.331			
Age at re-intubation	in hours	Mean±SD 228.41±114.853	Range 72 - 624	Mean±SD 465.60±173.135	Range 120-696	0.001*			

* Significant at P< 0.05
CPAP: Continuous positive airway pressure
HFNC: High flow nasal cannula

Table 4. Comparison of complications between the two groups

Complication		CPAP No.	CPAP %	HFNC No.	HFNC %	P-value
Pneumothorax		28	47.5%	31	52.5%	0.199
Suspected Necrotizing Enterocolitis		40	62.5%	24	37.5%	0.112
Nasal Trauma		48	90.6%	5	9.4%	<0.001*
Abdominal distension		53	58.2%	38	41.8%	0.312
Feeding intolerance		40	62.5%	24	37.5%	0.112
Bronchopulmonary dysplasia		11	27.5%	29	72.5%	<0.001*
Intraventricular Hemorrhage	All grades	20	74.1%	7	25.9%	0.027*
	Grade III / IV	11	61.1%	7	38.9%	0.549

*Significant at P < 0.05
CPAP: Continuous positive airway pressure
HFNC: High flow nasal cannula

Table 5. Comparison of secondary outcome of cases in the two groups

	CPAP Mean±SD	CPAP Range	HFNC Mean±SD	HFNC Range	P-value
Days to reach full enteral feeding.	10.50±3.442	4 - 18	11.79±5.340	4 - 26	0.056
Total duration of hospital stay (days).	25.81±14.645	6 - 64	27.17±13.967	8 - 63	0.512
	No.	%	No.	%	P-value
Discharge	94	54.0%	80	46.0%	0.517
Death	11	57.9%	8	42.1%	0.748

* Significant at P < 0.05

Table 6. Logistic regression analysis for risk factors associated with extubation failure

	B	S.E.	Waldχ^2	P-value	Odds ratio	95% C.I.for (OR) Lower	95% C.I.for (OR) Upper
Birth Weight	-0.208	0.653	0.101	0.750	0.812	0.226	2.920
Gestational Age	0.012	0.145	0.007	0.932	1.012	0.762	1.345
Prenatal Steroids	-1.444	0.535	7.288	0.007*	0.236	0.083	0.673
Surfactant use	-0.368	0.473	0.607	0.436	0.692	0.274	1.748
APGAR 5	-0.929	0.306	9.222	0.002*	0.395	0.217	0.719
Hours on Mechanical Ventilation	0.001	0.003	0.194	0.660	1.001	0.995	1.007
Late onset Sepsis	2.860	0.560	26.076	0.001*	17.457	5.825	52.320
Pneumothorax	-0.151	0.528	0.082	0.775	0.860	0.305	2.421
Age at start of non-invasive support (CPAP or HFNC)	0.005	0.056	0.009	0.925	1.005	0.901	1.122
Mode of non-invasive support (CPAP or HFNC)	-0.235	0.535	0.192	0.661	0.791	0.277	2.259
Oxygen saturation at extubation time	-0.305	0.099	9.495	0.002*	0.737	0.607	0.895

*Significant at P < 0.05

incidence of bronchopulmonary dysplasia was statistically significantly higher in the HFNC group, in comparison to that in the CPAP group. (Table 4)

The time to reach full enteral feedings was longer in patients extubated to HFNC (11.79±5.34 days), compared to patients extubated to CPAP (10.50±3.442 days); however, the difference was not statistically significant (P=0.056). In addition, there was no statistically significant difference regarding the total duration of hospital stay or outcome between the two groups (Table 5).

By logistic regression analysis, late-onset sepsis was the independent variable which was significantly associated with extubation failure (P<0.001, OR 17.457, 95% CI 5.825-52.320). 5-minute Apgar score, as well as the use of prenatal steroids and oxygen saturation at extubation time, were significantly inversely associated with extubation failure by logistic regression analysis (P=0.002, OR 0.395, 95% CI 0.217-0.719, P=0.007, OR 0.236, 95% CI 0.083-0.673 and P=0.002, OR 0.737, 95% CI 0.607-0.895, respectively) (Table 6).

Discussion

One of the daunting challenges in preterm newborns is the failure of respiratory and BPD which is associated with higher levels of mortality and morbidity (4). The belief in limiting the exposure to invasive mechanical ventilation is reflected by the current practices (5). It is possible to provide non-invasive ventilation using a set of different methods, including HFNC and NASAL CPAP. NASAL CPAP has been widely used as a method of providing noninvasive respiratory support to preterm neonates (6). Accordingly, the current study was planned as randomized controlled research for making a comparison between the efficacy and safety of preterm neonates' extubation in both HFNC and NASAL CPAP groups.

According to the characteristics of the population under study, it is revealed that the mean gestational age of the CPAP group (n=105) was 32.15± 1.651 weeks. On the other hand, the mean gestational age of the HFNC group (n=88) was 32.27±1.880 weeks. Furthermore, no statistically significant difference was detected between the two groups (P-value=0.636). This finding is consistent with a study carried out by Roberts et al. (7) where NASAL CPAP and HFNC were utilized as a mode of respiratory support in preterm neonates.

Half of the female patients were exposed to CPAP extubation and half of them were exposed to HFNC extubation. On the other hand, 59.1% of male patients were exposed to CPAP extubation, and the rest of them (40.9%) were exposed to HNFC extubation. The mean birth weight was 1.609±0.3837 gm in the HFNC group and 1.578±0.978 gm in the CPAP group. No statistically significant difference was found between the two groups in terms of the distribution of gender or the birth weight (P-value=0.203 & 0.352, respectively). In a similar vein, Yoder et al. (8) found no statistically significant difference between the groups under study in terms of their demographic characteristics.

Regarding the number of days spent on the non-invasive respiratory support, patients extubated to nasal CPAP spent significantly more days on CPAP, compared to days spent on HFNC after extubation (P-value=0.001). These results are in line with the findings reported by Badiee et al. (9) who showed that patients extubated to nasal CPAP remained on the study mode significantly longer than HFNC neonates. However, in the present study, the age at extubation to CPAP was significantly lower, compared to the age at extubation to HFNC (P-value=0.001), which could have contributed to the significant difference in the number of days spent on each mode of respiratory support (P-value=0.001).

Moreover, no difference was found between the two groups under study in terms of the total duration of supplemental oxygen therapy. This result is in accordance with that of Yoder, et al. (8) and Elkhwad, et al. (10) who found no significant difference in terms of the total duration of oxygen requirements till oxygen weaning which can be explained that the group spent significantly more days on CPAP needs fewer days on weaning oxygen after CPAP removal than HFNC group which needs more days on weaning oxygen after HFNC removal.

Using the logistic regression analysis for examining the independent variables which are related to the failure of extubation, there was no significant association between the age for starting non-invasive respiratory support and the failure of extubation (P-value=0.925). These results are consistent with those of Collins et al. (5) who revealed that there is no difference between CPAP and HFNC groups in terms of extubation failure rates. This may be explained by the selected narrow spectrum of the gestational age of 28-34 weeks

When comparing the two groups(CPAP and HFNC) in terms of extubation failure and the need for re-intubation, there was no statistically significant difference neither during the first post-extubation 72 h nor the first post-extubation week. This finding is in line with that of Taha et al. (11) and Elkhwad et al. (10) who showed that the HFNC is equally comparable to the nasal CPAP when it is used immediately after extubation in preterm neonates. Furthermore, no significant difference was found in terms of the need for re-intubation.

Regarding causes of extubation failure, they did not differ significantly between the two groups, except for the incidence of persistent severe retraction as a single cause of re-intubation, which was higher in the HFNC group, compared to that in the CPAP group (P-value=0.045). This finding is in agreement with the conclusion of a study conducted by de jongh et al. (12) where preterm neonates exhibited statistically significantly higher work of breathing indices and thoraco-abdominal asynchrony when supported with HFNC than nasal CPAP which can be ascribed to the higher incidence of persistent severe retraction in the HFNC group.

In the CPAP group, nasal trauma incidence was statistically significantly higher than that of the HFNC group (P-value=<0.001). These results are consistent with those of Collins et al. (13) who demonstrated that there is an association between nasal CPAP and the increased handling due to the mechanical complexities in fixing prongs properly, leading to an increase in agitation and nasal septal trauma risk. On the other hand, a humidified flow is provided by the HFNC to the nasal passages of neonates, and it facilitates the handling of newborns for procedures and care. This is due to the form of the connection which is a tinny nasal cannula.

Furthermore, in the HFNC group, BPD was

statistically and significantly higher, compared to that of the CPAP group. It can be ascribed to the fact that the delivery systems of HFNC neither measure the pressure of the airway nor impede the delivery of excessive pressure to the airway of neonates. The generation of unregulated distending pressure of the airway by the HFNC can result in lung injury either due to the overexpansion or due to atelectasis. In addition, it may contribute to developing BPD. These findings are in harmony with those of Taha et al. (11) who indicated that in preterm newborns, using HFNC is associated with a higher level of BPD risk.

In the CPAP group, the intraventricular hemorrhage (all grades) was statistically significantly higher than that of the HFNC group (P-value<0.027). Nevertheless, when severe intraventricular hemorrhage (grades III/IV) incidence is compared, no statistically significant difference was found between the two groups (P-value<0.549). These results are consistent with those of Hoffman et al, (14) who found no relationship between the two groups under study in terms of intraventricular hemorrhage outcome. Moreover, in line with the results of a study conducted by Wilkinson et al., there were no differences in the time to reach full enteral feedings, the total duration of hospital stay, and mortality between the two study groups (15).

Logistic regression analysis was performed to detect risk factors of failure of extubation from mechanical ventilation. Late-onset sepsis was the independent variable significantly associated with extubation failure (P-value <0.001). This finding is in accordance with the results of a study carried out by Miller and Dowd (16) who found an association between pre-existing sepsis and extubation failure due to the increased need of septic patients for oxygen and respiratory support. Logistic regression analysis demonstrated that the use of prenatal steroids was significantly inversely associated with extubation failure (P=0.007). Our results showed a slightly significant difference in the oxygen saturation level at the time of extubation in the HFNC group (mean=93.14 %), compared to the CPAP group (mean=92.45 %); nonetheless, both groups were within the recommended saturation goals ranging from 85%-98%.

5-minute Apgar score and oxygen saturation at extubation time were significantly inversely associated with extubation failure (P=0.002 and P=0.002, respectively). These findings are in consonance with the results of studies performed by Costa et al.(17) who concluded that low 5-minute Apgar scores, lower PO2, hypoxia, and marked hyperoxia exhibited associations with the extubation failure and re-intubation based on investigated outcomes for markers of successful extubation of their multivariate analysis.

On the other hand, our regression model revealed that weaning of mechanically ventilated preterm neonates to either HFNC or nasal CPAP was not significantly associated with extubation failure. These results are similar to the studies (11) and (10) that showed equal benefits regarding successful weaning from mechanical ventilation into nasal CPAP or HFNC.

Conclusion

HFNC use is comparable to the use of nasal CPAP in the immediate post-extubation period for preterm neonates born between 28 and 364 weeks of gestation with respiratory distress syndrome. HFNC appears to have similar efficacy and safety to nasal CPAP when applied immediately postextubation since the use of nasal CPAP and HFNC for extubation of preterm mechanically ventilated neonates were statistically significantly equal regarding the incidence of extubation failure. Neonatal sepsis was associated with a higher incidence of extubation failure, while the use of prenatal steroids, 5-minute Apgar score, and oxygen saturation at extubation time were significantly inversely associated with extubation failure. Moreover, there was a higher incidence of nasal trauma in the CPAP group, compared to the HFNC group. On the other hand, using HFNC was associated with a statistically significantly higher incidence of BPD, compared to CPAP. Furthermore, there were no differences in the incidence of intraventricular hemorrhage, feeding tolerance, time to reach full enteral feedings, the total duration of hospital stay, and mortality between the two study groups.

HFNC could be considered alternative respiratory support for newborns after extubation. However, a study with a larger sample size is needed, especially in extremely preterm newborns. More studies are required to establish this finding, and perhaps a multi-institutional study will be a beneficial next step in order to capture a larger sample size and different center policies.

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None.

Conflicts of interest

The authors declare that they have no conflict of interest regarding the publication of the current study.

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