Original Research Paper

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OBJECTIVE PREDICTORS OF READINESS FOR EXTUBATION IN NEONATES IN AN OBSERVATIONAL STUDY

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ABSTRACT **Background:** Mechanical ventilation plays a vital role in the treatment of neonates in NICU to prevent morbidity and mortality. A significant number of neonates require reintubation. There is paucity of evidence regarding assessment of readiness of patients for extubation, though several anecdotal studies have been undertaken. The present study aims to determine the predictors of extubation failure in neonates with respect to clinical, laboratory, and ventilator parameters. **Material & Method:** In this analytical cross-sectional study, 60 neonates on ventilatory support admitted in the NICU of SAMC & PGI, Indore requiring invasive ventilation for > 12 hours were analyzed. During the period of ventilation, their maximum ventilatory requirements were noted. Extubation failure was defined as requirement for reintubation within 48 hours of extubation. Prior to extubation, some key clinical, laboratory, and pulmonary mechanics parameters were assessed and values were noted. The differences in variables between the successfully and unsuccessfully extubated neonates were analyzed by Student t test and chi square test. **Results:** Out of the 60 neonates studied, 46 (76.7%) neonates had successful extubation and 14 (23.3%) required reintubation within 48 hours. Of the 14 neonates who failed extubation, 10 were preterm and 4 were term neonates. A significant correlation (P>0.05) was observed in extubation outcome and duration of ventilation, Oxygen Saturation Index, Mean Airway Pressure and Minute Ventilation which was observed 1 hour prior to extubation. However, there were no significant differences between the 2 groups with respect to clinical characteristics, maximum ventilator requirements, or laboratory parameters. **Conclusion:** Oxygen Saturatio Index, Mean Airway Pressure and Minute ventilation may serve as an objective indicator of readiness for extubation in neonates, in addition to the subjective indicators and clinical evaluations, which are presently used to determine readiness for extubation in everyday practice.

KEYWORDS : extubation, neonates, intensive intubation, CPAP, respiratory distress

INTRODUCTION

Advances in perinatal and neonatal care have significantly reduced neonatal morbidity and mortality rates. It is the introduction of widespread mechanical ventilation in the neonatal Intensive Care Units (NICU) during 1960s and 1970s[1] and its judicious use since, which has revolutionized the outcome and survival of sick newborns.[2] Mechanical ventilation is a life support procedure that contributes to increasing the survival of premature and full-term neonates and is one of the therapeutic resources most widely used in neonatal intensive care units (NICU). The indications for ventilation in term and preterm neonates are many—respiratory distress syndrome, asphyxia, meconium aspiration syndrome, and pneumonia being the most common.[3]

Despite its crucial role in reducing the mortality rate, mechanical ventilation is associated with morbidity, risks and complications prominently including bronchopulmonary dysplasia, ventilator associated pneumonia, prolonged hospital stay and nosocomial infections. Further, prolonged exposure to high FiO2 and inspiratory pressures results in an increased risk of bronchopulmonary dysplasia and related sequelae, thus emphasizing the criticality of extubating neonates as soon as possible.[4]

Reports from many anecdotal studies suggest that about one third of premature neonates fail extubation subsequently require reventilation.[5] These data indicate that criteria currently used to denote readiness to wean and extubate are relatively inaccurate. The current extubation criteria are subjective and based on arterial blood gas (ABG) evaluation, chest radiograph findings, clinical evaluation and laboratory parameters. No objective values are used to assess a patient's respiratory status. However, such parameters are not very well defined. In advent of same, the present study was aimed to identify and find the association of various parameters including clinical, laboratory and ventilator that predict successful or failed extubation in ventilated neonates.

MATERIAL & METHODS

This analytical cross-sectional study was undertaken on 60 neonates on ventilatory support admitted in NICU of Sri Aurobindo Medical College & PG Institute, Indore from April 2021 to September 2022 (18 months) qualifying the inclusion criteria.

Inclusion Criteria

All neonates invasively ventilated for more than 12 hours will be included at the time of their first extubation.

Exclusion Criteria

All the neonates who self-extubated were excluded from the study.

Procedure

After approval from the institutional ethical committee, pre-informed written consent was taken from the parents. A total of 60 neonates requiring invasive ventilation were studied.

Demographic data including birth weight, gestational age, indication for ventilation, and co-morbidities, if any, were recorded in a structured proforma and follow up was done. Clinical, laboratory and ventilatory parameters were studied and recorded.

Criteria For Extubation

The decision to extubate was made as per the unit protocol, which is as follows:

- On minimal ventilator settings (PIP<14mmHg, PEEP<6mmHg, FiO2 <30%)
- Good spontaneous effort
- Blood gas showing pH > 7.25, $PaCO_2$< 50

When the criteria for extubation were met, the neonate was prepared for extubation.

Caffeine was administered as per protocol in preterms < 32 weeks of gestational age. Sedation was not routinely used in all ventilated babies, however if used in certain conditions like PPHN etc., it was stopped 12 hours prior to extubation.

The following pre-extubation parameters were assessed for the first extubation only; subsequent extubations, if any, were not studied.

A. Clinical Parameters
a. Birth weight
b. Gestational age
c. Sedation
d. Phenobarbitone
e. Caffeine
f. Duration of ventilation
g. Indication of ventilation
h. Inotropes

B. Ventilator Parameters
a. Mean airway pressure
b. PIP
c. FiO2
d. Minute ventilation
e. Observed tidal volume
f. Compliance

C. Laboratory Parameters
a. Complete blood count, CRP, pH, Chest X-ray

Extubation failure was defined as of the need for invasive ventilation within 48 hours of extubation.

Criteria For Reintubation
- Recurrent apneic spells on CPAP/NIV.
- FiO_2requirement >60% on CPAP
- Blood gas $PaCO_2$>60, pH <7.25

Statistical Analysis
All data were recorded on a structured proforma and tabulated. Statistical analysis of the demographic data was performed using SPSS Software Version 20.0. The differences in the variables between the successfully and unsuccessfully extubated neonates were analyzed by Student t test and chi square test. P < .05 was considered to be statistically significant.

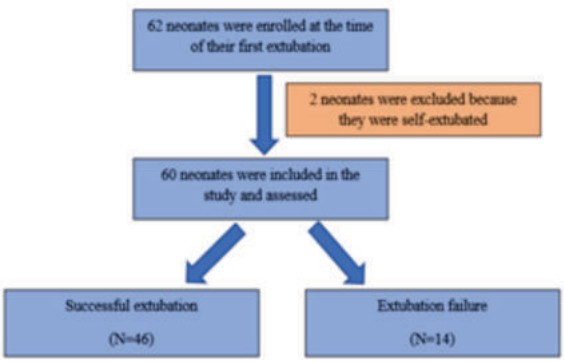


Figure 1. Plan Of The Study

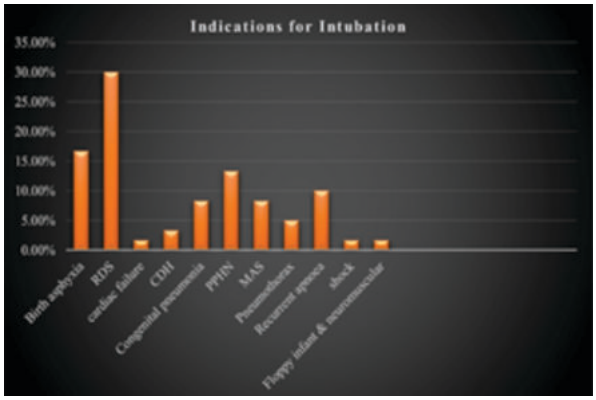
RESULTS
A total of 60 neonates, both term and preterm, requiring ventilation were studied. There were 15 (25%) term and 45(75%) preterm neonates. The reasons for ventilation are depicted in Graph 1. A statistically insignificant correlation was found between indication for ventilation and extubation outcome.

Of the 60 neonates on ventilation, 46 (76.7%) passed extubation and 14 (23.3%) required reintubation within 48 hours of extubation. Of the 14 neonates who failed extubation, 10 were preterm and 4 were term neonates. Of these 14 neonates, 8 were reintubated because of FiO2 requirement more than 60% whereas 3 were reintubated because of recurrent episodes of apnea and 3 was reintubated in view of severe respiratory acidosis (PaCO2>60).

As shown in Table 1, there was no statistically significant difference(P<0.05) found among 2 groups with respect to clinical parameters. Though the neonates who failed extubation had a lower mean birth weight and gestational age. The neonates were also analyzed to check if there was any difference in the outcome of extubation failure if they were on ionotropes, phenobarbitones, or sedatives and caffeine. A statistically insignificant correlation was observed (P>0.05)

Among ventilator parameters statistically significant correlation (P<0.05) was observed for duration of ventilation, Oxygen Saturation Index, Mean Airway Pressure and Minute Ventilation whereas an insignificant correlation (P>0.05) was observed for PIP, FiO2 and compliance. The neonates who failed extubation had higher duration of ventilation (53.143), higher OSI (6.750), higher MAP (12.600). It was found that the minute ventilation in those who failed extubation was significantly lower. Receiver operator curve of significant parameters suggested MAP>12, OSI>4.2 and minute ventilation <350 predicts extubation failure(depicted in graph 2,3 &4). There was a trend toward significance in the compliance, which was also lower in the group that failed extubation.

The blood parameters i.e., Hb, PCV, TLC, CRP and pH was non-significantly correlated (P<0.05).



Graph 1: Indications For Intubation

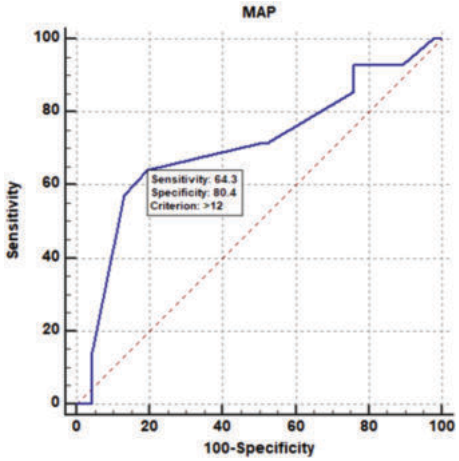
Table 1: The Association Between Clinical Parameters And Extubation Outcome

Variable		Extubation Outcome		Total	Statistical Analysis Test
		Successful N=46	Failure N=14		
CLINICAL PARAMETERS					
Gestational age	Preterm	35	10	45	X^2 = 0.124, df=1 P Value=0.724 Non Sig
		76.1%	71.4%	75.0%	
	Term	11	4	15	
		23.9%	28.6%	25.0%	
Birth Weight	Mean	1.854	1.572	-	t test= 0.248, df=1 P Value=0.724 Non Sig
	Standard deviation	0.808	0.735	-	
Sedation	Absent	37	13	50	X^2 = 1.193, df=1 P Value=0.275 Non Sig
		80.4%	92.9%	83.3%	
	Present	9	1	10	
		19.6%	7.1%	16.7%	
Phenobarbitone	Absent	43	11	54	X^2 = 2.650, df=1 P Value=0.104 Non Sig
		93.5%	78.6%	90.0%	
	Present	3	3	6	
		6.5%	21.4%	10.0%	
Inotropes	Absent	29	7	36	X^2 = 0.761, df=1 P Value=0.383 Non Sig
		63.0%	50.0%	60.0%	
	Present	17	7	24	
		37.0%	50.0%	40.0%	
Caffeine	Absent	24	5	29	X^2 = 1.164, df=1 P Value=0.281 Non Sig
		52.2%	35.7%	48.3%	
	Present	22	9	31	
		47.8%	64.3%	51.7%	

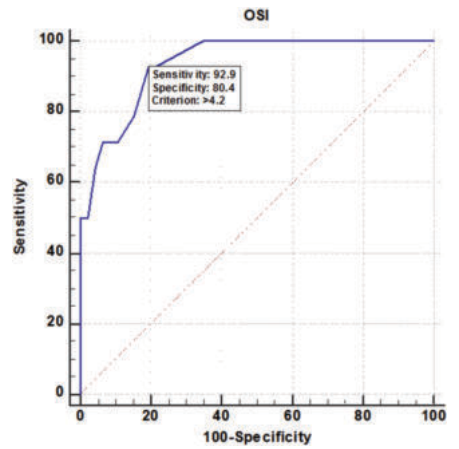
Table 2: Comparison Of Ventilatory Parameters With Extubation Outcome In Successfully And Unsuccessfully Extubated Neonates

Parameters	Extubation Outcome	N	Mean	Std. Deviation	T Test	P Value	Result
VENTILATORY PARAMETERS							
Duration of ventilation	Successful	46	42.239	14.888	-2.242	0.029	Sig
	Failure	14	53.143	19.114			
OSI	Successful	46	3.767	1.003	-7.949	0.000	Sig
	Failure	14	6.750	1.805			

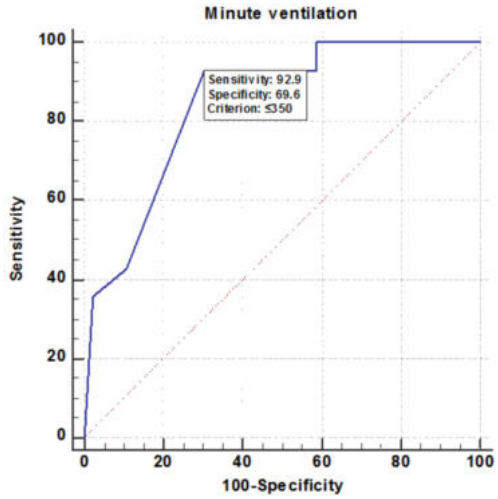
MAP	Successful	46	11.113	2.225	-2.173	0.034	Sig
	Failure	14	12.600	2.299			
PIP	Successful	46	16.696	1.724	-1.615	0.112	Non Sig
	Failure	14	17.571	1.950			
FiO2	Successful	46	35.587	7.960	-0.667	0.507	Non Sig
	Failure	14	37.214	8.097			
Minute ventilation	Successful	46	410.000	61.968	4.255	0.000	Sig
	Failure	14	335.714	36.101			
Observed tidal volume (ml/kg)	Successful	46	5.376	0.575	-0.335	0.739	Non Sig
	Failure	14	5.436	0.612			
Comp-liance	Successful	46	2.226	0.676	1.345	0.184	Non Sig
	Failure	14	1.950	0.658			



Graph 2: Roc For Mean Airway Pressure



Graph 3: Roc For Oxygen Saturation Index



Graph 4: Roc For Minute Ventilation

DISCUSSION

Determining reliable parameters to predict readiness for extubation and decrease the chances of reintubation has been a long-term need. Investigators across the world have studied various parameters to predict successful extubation.[6-12]In this study, we aimed to predict successful extubation with noninvasive bed side readily available parameters (clinical, laboratory, and ventilatory), which can be readily accessed from the graphics available on our present-day ventilators, without having to use any additional or costly equipment.

In the present study, among the clinical parameters (Gestational Age, birth weight, Sedation, Phenobarbitone, Inotropes, Caffeine) none were proved to be good predictor for successful extubation.

Among ventilator parameters which we studied 1 hour prior to extubation, we found a statistically significant correlation between duration of ventilation, OSI, MAP and minute ventilation among neonates who succeeded and failed extubation; whereas an insignificant correlation (P<0.05) was observed for PIP, FiO2 and compliance. Duration of ventilation had a statistically significant correlation with successful extubation (P=0.029). Neonates who required prolonged duration of ventilation (>48 hours) failed extubation when compared with neonates who had ventilator requirement of less than 48 hours. This was similar to results obtained by Baptistella AR et al.[19] In their study invasive mechanical ventilation duration was parameter that differed between the extubation success and failure groups. The risk of ventilator-related problems, hospitalisation expenses, morbidity, and mortality increase with the length of invasive mechanical ventilation.

Given that the severity of lung disease has the largest influence on postnatal outcomes, it is reasonable to revert to markers that determine the efficiency of gas exchange within the lungs. Such markers are the oxygenation index (OI) and oxygen saturation index (OSI), based on partial pressure of oxygen (pO_2) and on oxygen saturation (SpO_2), respectively. Both indices combine oxygen delivery (defined by mean airway pressure [MAP] and fraction of inspired oxygen [FiO_2]) and oxygen diffusion (pO_2 or SpO_2) into a ratio.[20,21] As the OSI could be monitored continuously and transcutaneously, in contrast to the commonly used OI that requires blood sampling, the OSI might be used for real-time and bedside guidance during the crucial first hours of life. Concurrently in our study we found OSI statistically significant among neonates who succeeded and failed extubation and thus it can be used as a predictor of extubation outcomes. Further, OSI is a good predictor for hypoxic respiratory failure as per previous studies, but no such studies done previously where it was assessed for predictor of successful extubation.

Further the minute ventilation among neonates who succeeded extubation was higher than those who failed extubation and this difference was statistically significant (P = 0.000). This was in concurrence with previous studies.[3,6,7] Chico M et al[3] in his study done on 51 neonates found minute ventilation, significantly higher in neonates who failed extubation compared to one who succeeded (P = .002). A study by Gillespie et al[6] used minute ventilation test (MVT) to assess a neonate's readiness for extubation. Neonates evaluated by the MVT were extubated in a significantly shorter period of time (mean of 8 h) than those evaluated clinically (mean of 36 h). Although the extubation failure rate was similar in both groups. Vento et al[7] studied spontaneous minute ventilation on endotracheal tube CPAP as a predictor of failed extubation in extremely low-birth-weight neonates. They found that there were no differences in dynamic lung compliance and lung resistance between the 2 groups, but the mean values of respiratory rate and spontaneous expiratory minute ventilation were significantly lower in the group that failed extubation. In this study no significant difference was found in mean tidal volumes between the 2 groups suggesting that tidal volume alone is not a good predictor of successful extubation as despite of low tidal volume neonates may have good capacity to maintain minute ventilation.

In this study MAP was found to be significantly higher in neonates who failed extubation. Thus MAP rather than PIP is a better indicator to check for readiness of extubation. But no such studies done previously where it was assessed for predictor of successful extubation

In this study, there were no significant differences in the other parameters i.e., PIP, FiO2 and compliance analyzed. This was similar to study done by Chico M et al.[3] who also observed compliance to be statistically insignificant; however, a trend towards being statistically

significant was observed as the P value was close to 0.05. Although these parameters (PIP, FiO2, compliance) tell about the condition of lung but individually they are not good predictors of successful extubation.

Apart from pulmonary mechanics, Hiremath et al[10]also studied clinical risk factors such as PDA, sepsis, and pneumonia, which could predict extubation failure. The incidence of sepsis, anemia, and pneumonia was found to be significantly higher in neonates who failed extubation. However, in our study a statistically insignificant correlation was observed for the blood parameters which were suggestive of sepsis and anaemia. Hence, these parameters can tell us about pulmonary function but they cannot predict outcome of extubation.

CONCLUSION

Mean airway pressure>12cmH_2O, Oxygen Saturation Index>4.2 and Minute ventilation<350ml/kg/min predicts extubation failure. These parameters may serve as an objective indicator of readiness for extubation in neonates, in addition to the subjective indicators and clinical evaluations, which are presently used to determine readiness for extubation in everyday practice.

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